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Responding to First Responders:
A Proposal for a Smallpox Vaccine Injury Compensation Program

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Abstract:

In December 2002, President Bush announced a plan to provide smallpox vaccinations to first responders—individuals who would be on the front lines in the event of a biological attack. To date, the plan has been unsuccessful because many first responders are unsatisfied with the protections provided for adverse reactions. In particular, a new federal statute exempts manufacturers from liability and only permits negligence claims against the United States. Additionally, many states have not determined the scope of their workers' compensation coverage. As a result, there is a rising demand for a federal program to compensate for smallpox vaccine injuries. This Article analyzes three federal compensation programs and recommends a smallpox compensation program based on lessons from these programs. Finally, it outlines two new proposals by Representative Waxman and by the Department of Health and Human Services.

On Thursday October 4, 2001, Florida health officials announced that doctors hospitalized a 63-year-old man suffering from pulmonary anthrax.¹ Quick to allay public fears following September 11, White House officials dismissed the possibility of intentional transmission.² One day later the man passed away.³ After a co-worker also tested positive for anthrax, the FBI began to suspect bioterrorism.⁴

Over several months, fear of anthrax gripped the nation. Letters containing anthrax were sent to Senator Daschle,⁵ Senator Leahy,⁶ and NBC news anchor Tom Brokaw.⁷ In the end, five people died and anthrax spores contaminated several buildings. Once a hypothetical threat, the anthrax attacks demonstrated the disruptive potential of bioterrorism and engrained it in the public consciousness. Though the anthrax attacks

¹See Gina Kolata, *Florida Man is Hospitalized with Pulmonary Anthrax*, N.Y. TIMES, Oct. 5, 2001, at A16.

²*Id.* At a press conference, Secretary of Health and Human Services Tommy Thompson declared that “[I]t is an isolated case, and it is not contagious. There is no terrorism.” *Id.*

³Dana Canedy and Nicholas Wade, *Florida Man Dies of Rare Form of Anthrax*, N.Y. TIMES, Oct. 6, 2001, at A9.

⁴Dana Canedy and Alex Kuczynski, *A Nation Challenged: A Medical Mystery; Second Case of Anthrax Leads F.B.I. to Inquiry*, N.Y. TIMES, Oct. 9, 2001, at A1.

⁵Sheryl Gay Stolberg & Alison Mitchell, *A Nation Challenged: The Overview; Letter Containing Anthrax Sent to U.S. Senate Leader*, N.Y. TIMES, Oct. 16, 2001, at A1.

⁶Philip Shenon, *A Nation Challenged: Discovery on Anthrax; Suspicious Letter to a 2nd Senator*, N.Y. TIMES, Nov. 17, 2001, at A1.

⁷David Barstow, *A Nation Challenged: The Incidents; Anthrax Found in NBC News Aide*, N.Y. TIMES, Oct. 13, 2001, at A1.

were frightening, many officials expressed relief that the pathogen was not smallpox.

Clearly, the country was unprepared to handle a large scale bioterrorist attack. Before the anthrax attacks, public health policy based on a perceived low probability of bioterrorism left the country vulnerable. In fact, a June 2001 report to the Centers for Disease Control and Prevention (the “CDC”) by the multidisciplinary Advisory Committee on Immunization Practices (the “ACIP”) recommended against resuming smallpox vaccinations.⁸ Nevertheless, they cited a potential need to alter this policy if the threat of bioterrorism increased. Following September 11, the CDC asked ACIP to reevaluate their proposal. ACIP responded by recommending a limited vaccine program to health officials who would interact with victims of a smallpox attack.⁹

Soon after the recommendations, President George W. Bush signed the Homeland Security Act of 2002 (the “HSA”) into law.¹⁰ Most notably, the Act merged twenty-two federal agencies into one cabinet level agency called the Department of Homeland Security. Among additional provisions, the Act gave the Secretary of Health and Human Services (the Secretary of HHS) and the Secretary of Homeland Security power to develop policies in response to biological and chemical threats.¹¹

The White House quickly used this authority to announce a smallpox vaccination plan (the “Vaccination Plan”) similar to the ACIP proposal.¹² The plan called for the vaccination of all military and government personnel who are or will be deployed in high-risk areas. Additionally, the plan calls for the formation and vaccination of Smallpox Response Teams who would immediately respond to a smallpox attack. These first responders include physicians, health care workers, law enforcement officers and firefighters.

While vaccinations are mandatory for military personnel, they are optional for first responders. As currently

⁸Advisory Committee on Immunization Practices, *Vaccinia (Smallpox) Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP) 2001*, 50 MORBIDITY AND MORTALITY WKL’Y RPT. 1 (June 22, 2001).

⁹Advisory Committee on Immunization Practices, *Recommendations of Using Smallpox Vaccine in a Pre-Event Vaccination Program*, 52 MORBIDITY AND MORTALITY WKL’Y RPT. 1 (Feb. 26, 2003). [hereinafter ACIP Proposal]

¹⁰See Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (codified in scattered sections of 6 U.S.C, 7 U.S.C. and 26 U.S.C.).

¹¹*Id.*

¹²Remarks Announcing the Smallpox Vaccination Plan, 38 WEEKLY COMP. PRES. DOC. 2162-63 (Dec. 13, 2002).

outlined, the non-military plan has two phases. In the first phase, 500,000 health care workers will receive the smallpox vaccine.¹³ Most of these people will be state health officials and groups of doctors from various hospitals within each state. In the second phase, another 10 million individuals will be vaccinated. This phase broadens the scope of vaccinations to police, firefighters, and emergency personnel.

Soon after the announcement, various government agencies began its implementation. On January 22, the CDC shipped 20,000 doses of the smallpox vaccine to Connecticut, Nebraska, Vermont and Los Angeles County.¹⁴ Two days later, following procedures prescribed by the HSA, Secretary of HHS Tommy Thompson signed a declaration beginning voluntary vaccinations.¹⁵ On the same day, four Connecticut doctors were the first volunteers to be vaccinated.¹⁶

At the announcement for the Vaccination Plan, Secretary Thompson promised to complete the initial stage of vaccination within thirty days.¹⁷ Despite the optimism and swift response within the government, the public has been more cautious. In particular, a growing number of states,¹⁸ hospitals,¹⁹ and medical groups have expressed reservations.²⁰ While there has not been an active smallpox vaccine program in the United States for over twenty years, the epidemiological and anecdotal data suggests that the vaccine has very serious side effects. There are two major concerns with vaccinating first responders. First, some public health experts worry that first responders could inadvertently infect hospital patients or family members.

While first responders may be willing to individually assume the risks from vaccination, the experts are

¹³Donald G. McNeil, *Smallpox Inoculations Begin With 4 Connecticut Doctors*, N.Y. TIMES, Jan. 25, 2003, at A10.

¹⁴*Id.*

¹⁵See Declaration Regarding Administration of Smallpox Countermeasures, 68 Fed. Reg. 4212 (Jan. 28, 2003).

¹⁶McNeil, *supra* note 13, at A10. Originally, Connecticut planned to publicly vaccinate 8 to 20 members of the state health department's Genesis Team to increase public confidence. At the last minute, several members of the team refused vaccinations because the nurses union was concerned that the state was rushing the vaccinations. *Id.* See also, William Hathaway, *Union Recommends Nurses Refuse Today's Smallpox Shots*, THE HARTFORD COURANT, Jan. 24, 2003, at B1.

¹⁷See Ceci Connolly, *Bush Smallpox Plan Near Standstill; Medical Professionals Cite Possible Side Effects, Uncertainty of Threat*, N.Y. TIMES, Feb. 24, 2003, at A6.

¹⁸See, e.g., Sabin Russell, *State Health Chief Takes Issue With Smallpox Plan*, S.F. CHRON., Jan. 23, 2003, at A4. (stating that a lack of federal guidance caused California Department of Health Service Director Diana Bonta to send a letter to the CDC saying that "a lack of federal guidance is delaying California's ability to complete our readiness effort").

¹⁹Pamela Ferdinand & Ceci Connolly, *Turnout Low at Launch of Domestic War on Smallpox; Conn. First State to Carry Out Bush's Immunization Campaign*, WASH. POST, January 25, 2003, at A12.

²⁰*Id.*

concerned about imposing these risks on others. Many physicians believe there are currently more immuno-compromised individuals than there were when smallpox vaccinations ended. In particular, AIDS was a fledgling disease and chemotherapy was much less common. These individuals would be at a greater risk of suffering serious side effects if exposed to the smallpox vaccine.

The second concern is the significant uncertainty surrounding compensation for vaccine injuries. In many states, it is currently unclear whether workers' compensation covers vaccine-related injuries resulting from participation in a voluntary program. Many insurers only cover illnesses or injuries resulting from required work. Additionally, the HSA protects the government, vaccine makers, and those administering the vaccine from liability.²¹ In order to recover damages, an injured party must prove negligence. Therefore, it is not clear that injured parties will receive compensation either through workers' compensation or the tort system. In response to this concern, there have been calls for a compensation program from various quarters. Some hospitals have announced that they will not participate in the Vaccination Plan until the government resolves the compensation issue.²² Responding to the decline in hospital demand, some states have significantly scaled back their vaccination plans.²³ In response to these events, twenty-three U.S. senators sent a letter to President Bush stating that the government must provide more medical help to those receiving vaccinations.²⁴ Additionally, both Senator Daschle and Senator Byrd have introduced measures in the Senate calling for compensation. Unfortunately, both pieces of legislation only mention the need for compensation, offer no substantive provisions, and have received little support. Even the Institute of Medicine (the "IOM"), a less political organization, recommended that the Vaccination Plan address the compensation problem.²⁵ With

²¹ See 42 U.S.C. §233(p).

²²For example, nine of the twelve largest hospitals in Colorado have initially decided to not vaccinate their workers. *Smallpox: Many Colorado Hospitals May Not Inoculate Workers*, VACCINE WEEKLY, Jan. 29, 2003, at 17.

²³Ferdinand & Connolly, *supra* note 20. While initially planning to vaccinate 12,000 people, Alabama adjusted the estimate to 2,000 to 5,000. *Id.*

²⁴Stephen Smith, *After Three Decades, Vaccination Makes a Debated Return*, BOSTON GLOBE, Jan. 24, 2003, at A6. In the letter, the senators stated that "[I]t is wrong to ask millions of Americans to face the risks of smallpox vaccination without doing all we can to protect their health and safety." *Id.*

²⁵See Institute of Medicine, REVIEW OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S SMALLPOX VACCINATION PROGRAM IMPLEMENTATION (2003). The IOM report adopts an interested posture to their argument. Their biggest concern

this increased scrutiny, some public health experts have started to question whether there is even a sufficient risk of biological attack to justify the dangers of immunization.²⁶

It seems clear that the Vaccination Plan will fail without a resolution to the compensation problem. At Secretary Thompson's one month target date, it has fallen far short of his goal. Only 4,200 people, less than 1% of the goal, had been vaccinated by February 22.²⁷ These low numbers and the increased public dissent illustrate the necessity for public discussion about society's responsibilities for vaccine injuries. This article attempts to contribute to the discussion in several ways. First, it describes the current legal regimes governing compensation for smallpox vaccine injuries. Second, it presents the policy issues with a particular focus on the issue of compensation and historical approaches to compensation programs. Finally, this Article recommends a complementary compensation system for vaccine injuries. Assuming that significant compliance by first responders is desirable, it recommends a compensation regime with the following features:

(1) manufacturer exemption for liability with right of contribution by the U.S. government for negligence, (2) compensation for designated first responders and secondary transmissions from first responders, (3) no compensation for non-first responders, (4) tort-like approach with proof of causation, (5) table causation, (6) table compensation, (7) federal control, and (8) administration by special masters.

In accomplishing these goals, this Article has seven parts. Following this introduction, Part II provides a background of smallpox, the smallpox vaccine, and bioterrorism. Next, Part III outlines current legal regimes for compensating smallpox vaccine injuries. In particular, it focuses on the availability of compensation through common law tort theories, workers' compensation, and HSA Section 304.

With the current law as background, the next three sections describe and analyze three different historical

with the uncertainty is informed consent. It is not clear whether individuals can make an informed decision to receive a vaccine if the compensation program has not been worked out. *See id.*

²⁶*Id.* Dr. Linda Rosenstock, dean of the UCLA School of Public Medicine, stated "My concern is we had a politicization of the scientific process. One might defend making national security actions and war plans on information that can't be shared with the public. I just can't see any justification for making public health policy in the same mindset of secrecy." *Id.*

²⁷Connolly, *supra* note 17, at A6.

compensation programs. Part IV discusses the Swine Flu Act of 1976, which exempted manufacturers from liability and compensated parties for injuries resulting from a national effort to vaccinate against a virulent strain of the flu. It is an important model for the current discussion because its operation was similar to HSA Section 304. Next, Part V discusses the National Childhood Vaccine Injury Act (the “NCVIA”), which established a no-fault compensation system called the Vaccine Injury Compensation Program (the “VICP”) for children injured by childhood vaccines such as the measles, mumps, and rubella booster.²⁸ In addition, it implemented provisions to facilitate recovery and expedite the claim process. It is also important because several Senators have suggested using the NCVIA as a template for a smallpox compensation program. Part VI then analyzes the 9/11 Victim’s Compensation Fund (the “9/11 VCF”). This newly enacted compensation system has received much public scrutiny and offers several lessons for constructing a compensation system. Finally, Part VII analyzes these possibilities and recommends a limited compensation program for smallpox vaccine injuries.

Part II: Background of Smallpox

In order to craft a compensation system, it is important to understand some background on smallpox and its history. The first section provides a simple introduction to the clinical manifestations of smallpox followed by the history of smallpox in the second section. The third section then describes the smallpox vaccine and its production while the fourth section provides a description of the common side effects of the smallpox vaccine. Finally, the fifth section provides an overview of the threat of smallpox as a biological weapon.

A.

Clinical Signs of Smallpox

²⁸42 U.S.C. §300aa-1-34.

Smallpox is a specifically human disease caused by the variola virus.²⁹ Viral transmission occurs through inhalation of air droplets from an infected individual.³⁰ Twelve to fifteen days after infection, the individual begins to experience fever and joint pain. A rash on the face and extremities develops several days later. During the initial days of infection, people often confuse smallpox with chickenpox.³¹ Eventually the uniformity of the pustules and their concentration around the face and extremities distinguishes smallpox. When the body mounts an effective immune response, scabbing develops and eventually results in the characteristic pitted scar.

In addition to causing disfigurement, smallpox has a relatively high mortality rate. The exact rate varied because of several factors. First, there are two forms of variola that vary by severity of illness: variola major and variola minor.³² While individuals with variola minor may have the same number of pustules as individuals with variola major, they have a less systemic reaction and are often ambulatory. Individuals infected with variola minor died less than one percent of the time whereas those suffering from variola major died fifteen to twenty percent of the time.³³ Second, the severity of the smallpox depended on the strain. Individuals suffering from the African form had a twenty to thirty percent lower mortality rate than those suffering from the Asian form.³⁴ Finally, children died more often than adults. In Asia, mortality rates were forty to fifty percent for children compared with twenty percent for adults.³⁵

When death occurs, it is normally from one of two causes. Five to ten percent of smallpox patients develop

²⁹D.A. Henderson, *Smallpox: Clinical and Epidemiological Features*, 5 EMERGING INFECTIOUS DISEASES 537 (1999). The variola virus, along with the viruses causing vaccinia, cowpox and monkeypox, belongs to a genus of viruses known as *Orthopoxvirus*. These four viruses can infect humans and are indistinguishable in cell cultures.

³⁰Donald A. Henderson & Bernard Moss, *Smallpox and Vaccinia*, VACCINES (Stanley A. Plotkin & Walter A. Orenstein eds., 1999). This mode of transmission made smallpox an excellent candidate for eradication. There was no animal reservoir so the outbreak would end when no more people were available for infection. Additionally, transmission does not occur until the onset of rash. A person with smallpox, however, would have a fever and be bedridden before onset of the rash. As a result, fewer people come in contact with a contagious individual.

³¹F. FENNER ET AL., SMALLPOX AND ITS ERADICATION 105 (1988).

³²*Id.* at 96. Despite the extensive history of smallpox, researchers first noticed the existence of variola minor at the end of the Nineteenth Century. In an early epidemiological study, researchers observed the existence of a “mild” variety that never reverted to the more severe form. *Id.*

³³*Id.* at 133.

³⁴*Id.*

³⁵*Id.* at 134.

a hemorrhagic form that almost always results in death.³⁶ This extreme form of smallpox results in bleeding from the skin and intestinal tract. The remaining deaths normally result from a systemic reaction to the virus that occurs one to two weeks after onset of the disease.³⁷

B.

A Brief History of Smallpox

There is some evidence that ancient civilizations suffered from smallpox. The earliest evidence is three 3000 year-old Egyptian mummies with lesions clinically consistent with smallpox.³⁸ Unfortunately, these findings cannot be corroborated from other sources. Though Egyptians generally wrote about medical subjects, archeologists have found no written evidence of smallpox. In India, however, the word *masurika* meaning smallpox appears in several medical texts from the beginning of the Christian era.³⁹ Additionally some scholars point to the mention of “scabs” as evidence of a smallpox epidemic devastating Alexander’s army in 327 B.C. as it camped along the Indus River.⁴⁰ There is also scattered evidence of smallpox in other cultures around this time period. Over the next several hundred years, medical knowledge increased. By the end of the first millennium, there were more extensive writings on smallpox. Interestingly, until the end of the 1700’s, one of the most influential texts on smallpox in Europe was a book from 910 A.D. by a Mesopotamian physician named Al-Razi.⁴¹

While the origin of smallpox is uncertain, its introduction to Europe can be traced to the Crusades in the

³⁶D.A. Henderson, *supra* note 29, at 537.

³⁷*Id.*

³⁸“Inspection of the mummy revealed a rash of elevated ‘pustules’, each at about two to four millimeters in diameter, that was most distinct on the lower face, neck, and shoulders, but was also visible on the arms.” D.R. Hopkins, *PRINCES AND PEASANTS, SMALLPOX IN HISTORY* (1983).

³⁹F. FENNER ET AL., *supra* note 31, at 211. The first description of severe *masurika* appears in the writings of a physician in the 7th Century A.D. A more extensive discussion of *masurika* was written in the following century with details of smallpox, chickenpox and measles.

⁴⁰*Id.*

⁴¹*Id.* In this text, al-Razi noted that smallpox was most common in the spring and disproportionately affected children.

Twelfth and Thirteenth Centuries.⁴² Christians moving between Europe and southwestern Asia during this time spread smallpox throughout Europe. As the population grew in Europe, smallpox became endemic. There are substantial records from Fifteenth Century France of children suffering from smallpox. In fact, the French originated the name smallpox by calling the disease “la petite verole” to distinguish it from “la grosse verole” or syphilis. The English adopted a similar nomenclature resulting in the name “smallpox” while they called syphilis the “great pox.”⁴³

By the late Eighteenth Century, smallpox was a common cause of death in Europe. During the last two decades of the Eighteenth Century, it was responsible for ten percent of the deaths in London.⁴⁴ The trend soon changed in 1796 when Edward Jenner developed the process of inoculation. Jenner observed that cowmaids exposed to cowpox did not suffer from smallpox and postulated that the cowpox exposure conferred immunity to smallpox. In order to test his hypothesis, Jenner transferred cowpox between individuals by inoculating a person with the material from a cowpox lesion.⁴⁵ The newly infected person was resistant. This process of inoculation quickly spread throughout Europe with arm-to-arm contact being the preferred method. Despite the early success of inoculation, a significant dissent mounted because there were problems with reoccurrence and transportation of stable vaccine. By the mid-1850’s, however, the harvest of material from infected calves replaced arm-to-arm inoculation making transportation much easier.

With a better source of vaccine, the number of vaccinations in Europe increased while the incidence of

⁴²*Id* at 214.

⁴³The English and French called syphilis the “great pox” because the lesions were larger and more likely to be found on adults.

⁴⁴FENNER ET AL., *supra* note 31, at 213. From 1806 to 1810, smallpox killed over 800,000 Russians and infected another 8 million.

⁴⁵Jenner called the process vaccination and the material vaccine from *vacca*, the Latin word for cow. Henderson & Moss, *supra* note 30.

smallpox decreased. By the end of World War I, most of Europe was smallpox free.⁴⁶ The less developed tropical areas of the world were not as successful. Many countries still relied on arm-to-arm inoculation. Those individuals who harvested from calves had only several days before the tropical heat inactivated the vaccine. In the late 1940's, however, a new method of freeze-drying was introduced that produced a more stable vaccine.⁴⁷

In 1958, U.S.S.R Deputy Minister of Health Viktor Zhhdanov presented a report to the World Health Assembly arguing that smallpox eradication was feasible.⁴⁸ The following year, the World Health Assembly voted to start the eradication program. After several years of limited support and disappointing results, the World Health Organization (the WHO) convened a committee to discuss the program. In 1966, the Director General of the WHO recommended a budget increase to mount a more effective eradication campaign.⁴⁹ The intensified Global Eradication Program began the following year. It focused on two improvements: (1) using potent and stable vaccines in at least 80% of the population and (2) developing a system to detect and contain outbreaks. This new approach slowly yielded results with the last naturally occurring outbreak of smallpox occurring October 26, 1977 in Merka, Somalia.⁵⁰ One year later, there were two cases of English laboratory workers being infected.⁵¹ In 1980 the World Health Assembly announced the eradication of naturally occurring smallpox.⁵²

⁴⁶*Id.*

⁴⁷*Id.*

⁴⁸F. FENNER ET AL., *supra* note 31, at 367. The report presented a five year timetable for eradication: two years of vaccine preparation, two years of vaccination, and one year of revaccination. In an interesting twist, the report began with a quote from Thomas Jefferson to Edward Jenner stating that "[I]t is owing to your discovery...that in the future the peoples of the world will learn about the disgusting smallpox disease only from ancient tradition."

⁴⁹*Id.* at 409. The proposal increased the overall budget of the WHO by twenty-two percent.

⁵⁰See World Health Organization, *Declaration of Global Eradication of Smallpox*, 55 MORBIDITY AND MORTALITY WEEKLY REPORT 145 (1980).

⁵¹F. FENNER ET AL., *supra* note 31, at 349.

⁵²See World Health Organization, *supra* note 50, at 145.

C.

Smallpox and Biological Warfare

An interesting parallel to the history of smallpox is the history of biological warfare and the use of smallpox. Since ancient times, there are examples of soldiers using biology to increase the lethality of their conventional methods of killing. For example, Romans often dipped their swords in manure or rotting carcasses and Scythian archers would plunge their arrows in feces or corpses before battle.⁵³ In fact, this practice is the origin of the word “toxin,” which is derived from the Greek word *toxon* meaning bow.⁵⁴ Perhaps the most credible account of an early biological attack is the siege of Kaffa in 1346 A.D.⁵⁵

There is also some history of biological warfare in the United States. While there is no evidence of intentional biological warfare before the 1700s, the natural transmission of disease had devastating consequences on Native Americans. The initial settlement of the United States brought Eurasian disease like smallpox, measles, and influenza. The subsequent slave trade brought additional diseases such as malaria and yellow

⁵³Croddy, CHEMICAL AND BIOLOGICAL WARFARE 219 (2002). These primitive examples differ from modern biological warfare in several respects. First, the method of killing remained unchanged. The soldier would still have to wield his sword or shoot his arrow. Second, there is uncertainty about the eventual cause of death. Pretreatment undoubtedly increased the lethality of a wound by inducing infection in the victim. There is no way to determine, however, whether the victim would have survived the wound but for the biological agent.

⁵⁴Joseph T. Shipley, DICTIONARY OF WORD ORIGINS, at p. 195. More reflective of the modern biological warfare, some ancient soldiers would use biology as the mode of killing. During the Second Macedonian War, around 190 B.C., Hannibal’s men would throw poisonous snakes onto King Eumene’s ships. Unlike the Scythian arrows, it was the bite of the snake rather than its impact that delivered the mortal blow. In another example, retreating Greek soldiers would often place human or animal remains in drinking wells. It is unclear whether their intent was to infect with disease or to deny potable water. In both case, however, the mode of delivery and the means of death was the biological agent. See Mark Whellis, *Biological Warfare Before 1914* in BIOLOGICAL AND TOXIN WEAPONS: RESEARCH DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1914 (Erhard Geissler & John Ellis van Courtland Moon Eds.) 1991.

⁵⁵*Id.* at 13. Most of the details of the siege are based on eyewitness accounts relayed to an Italian, Gabriele de’ Mussi. Kaffa, now known as Feodosia in the Ukraine, was an important Genoese city on the Crimean coast facing the Black Sea. It served as a hub between maritime Mediterranean trade and overland caravans to the Far East. The thriving city was an attractive target to invading Mongol troops. Kaffa, however, was protected by two concentric walls and difficult to overrun. The Mongols fought for over a year but eventually succumbed to the plague that killed them by the thousands. Before retreating, however, the Mongols loaded their dead into catapults and flung them into the city. Estimates of the death toll in the Kaffa region are as high as 85,000 people. It is unclear, however, whether death resulted from the introduction of the diseased corpses or from rats migrating from the surrounding areas to the city. *Id.* at 10-17

fever. The novelty of these diseases ravaged the Native American population because they lacked previous exposure meaning there was no previous natural selection for resistance. Additionally, experts suggest that the Native American population had little genetic diversity.⁵⁶ The result was a sweeping epidemic of disease that roughly tracked European settlement patterns.⁵⁷

The first documented case of intentional transmission occurred during the French and Indian War. In 1763, the French already had surrendered Canada and much of the British troops had returned to England. Pontiac, chief of the Ottawas, had formed a loose confederation to push the British out of Canada and east of the Alleghenies. In what is known as the Pontiac Rebellion, the confederation captured eight forts and threatened further advance. Fort Pitt, now modern-day Pittsburgh, was under siege by both the Native Americans and an outbreak of smallpox. The commanders responded by using the one threat against the other. General Amherst writing to the regional field commander Colonel Bouquet ordered that “you will do well to try to inoculate the Indians by means of blankets, as well as to try every other method that can serve to extirpate this execrable race.”⁵⁸

During the 1800’s, the field of microbiology grew rapidly. By the end of the century, researchers discovered many common bacteria and understood their mechanism of action. Nevertheless, there was only small progress in the development of biological weapons. While World War I witnessed the use of chemical weapons on the battlefield, there was very little use of biological weapons.⁵⁹ In 1925, numerous countries ratified The Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases and

⁵⁶F.L. Black. *Why Did They Die?* 258 Science 1739 (1992). Smallpox epidemics typically had a mortality rate of twenty to forty percent in European populations. In Native American populations, the fatality rate has been reported as high as ninety percent.

⁵⁷D.R. Snow *Microtechnology and Demographic Evidence Relating to the Size of pre-Columbian North American Indian Populations* 268 Science 1601 (1995). There is no evidence that this devastation was the result of intentional infection. Nevertheless, evidence suggests that settlers understood the extent of the effects. John Winthrop, the first Governor of Massachusetts Bay Colony, stated in a letter to a member of the English Parliament that “for the natives, they are neere all dead of the small Poxe, so as the Lord hath cleared our title to what we possess.” Whellis, *supra* note 54, at 15.

⁵⁸*Id.* at 24.

⁵⁹The Germans largely used biological weapons for sabotage. In 1915-17, while the United States was still neutral, German agents cultivated anthrax and glanders bacteria. Evidence indicates that they attempted to infect some animal populations on the Eastern seaboard. See Mark Whellis, *Biological Sabotage in World War I* in BIOLOGICAL AND TOXIN WEAPONS: RESEARCH DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1914 (Erhard Geissler & John Ellis van Courtland Moon Eds.) 1991.

of Bacteriological Methods of Warfare (the “Geneva Protocol”).⁶⁰ Surprisingly, the Germans adhered to the Geneva Protocol prior to and during World War II.⁶¹ On the other hand, the Japanese developed an extensive program and used biological agents on the Chinese. Estimates of the number of Chinese killed vary greatly with some estimates over 100,000.⁶² Acting on the perceived threat of a biological attack by the Axis, Allied nations such as the United States, Canada, and Great Britain developed active biowarfare programs.⁶³ Following World War II, both the United States and the Soviet Union continued to carry on extensive programs.

Throughout the Cold War, smallpox research was an integral part of the Soviet and U.S. biological weapons programs. When the WHO recommended that countries cease smallpox vaccination in 1980, it also recommended that participating countries destroy their stocks of variola virus or give them to the WHO.⁶⁴ All countries reportedly complied with this mandate. The WHO also designated two laboratories to house serve as a depository for the last stocks of smallpox: the Institute of Virus Preparations in Moscow, Russia and the Center for Disease Control and Prevention in Atlanta, Georgia.⁶⁵

Despite this system for consolidating smallpox, there is substantial concern that a terrorist could use smallpox in a biological attack. Recent reports indicate that the Soviets weaponized large quantities of smallpox in the early 1980’s.⁶⁶ Experts believe that the Soviet program annually produced several tons of smallpox virus. Further, there are reports that Russia continues their predecessor’s bioweapons program. The stability of Russia alarms Western experts for several reasons. First, there is concern that any remaining biological

⁶⁰*Id.*

⁶¹See Sheldon Harris, *The Japanese Biological Warfare Programme* in BIOLOGICAL AND TOXIN WEAPONS: RESEARCH DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1914 (Erhard Geissler & John Ellis van Courtland Moon Eds.) 1991.

⁶²*Id.* at 39.

⁶³See Gradon B. Carter and Graham S. Pearson, *British Biological Warfare and Biological Defence 1925-45* in BIOLOGICAL AND TOXIN WEAPONS: RESEARCH DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1914 (Erhard Geissler & John Ellis van Courtland Moon Eds.) 1991 and Donald Avery, *Canadian Biological and Toxin Warfare Research, Development and Planning 1925-45* in BIOLOGICAL AND TOXIN WEAPONS: RESEARCH DEVELOPMENT AND USE FROM THE MIDDLE AGES TO 1914 (Erhard Geissler & John Ellis van Courtland Moon Eds.) 1991.

⁶⁴See M. Radesky, *Smallpox: A History of the Rise and Fall*, 18 PED. INFECTIOUS DISEASE J. 85 (1999).

⁶⁵See *id.*

⁶⁶See Ken Alibek, BIOHAZARD 109-22 (1999).

materials could fall into the wrong hands. Second, there is concern that expert scientists will free-lance their services to the highest bidder. Both concerns are elevated by the decreasing financial support for a once sophisticated Russian science program. In addition to the Russian threat, there is also a possibility that a rogue nation or terrorist network could acquire smallpox from a different source. In a recent Senate committee hearing, Senator Bill Frist stated that ten to fourteen countries have developed offensive biological weapons programs.⁶⁷

Smallpox in the wrong hands is frightening because it is an effective biological weapon. It can be produced in large quantities at relatively low cost.⁶⁸ Additionally, it is very stable and is easily dispersed in an aerosolized form that only requires a small amount to cause infection.⁶⁹ Finally, unlike anthrax, it is contagious. Some experts estimate that smallpox could spread by a factor of ten to twenty times each generation. This estimate would mean that an initial infection of fifty individuals could spread to 400,000 by the third generation.

D.

The Smallpox Vaccine

A first line of defense against a smallpox attack is the smallpox vaccine. While there are currently several vaccines available, the Vaccination Program uses the Wyeth Dryvax vaccine. This vaccine is the only one available that the FDA approved for use.⁷⁰ Wyeth Laboratories discontinued production of Dryvax in 1982 and has not distributed the vaccine to civilians since 1983.⁷¹ In 1990, the military discontinued vaccinating

⁶⁷*The Smallpox Vaccination Plan: Challenges and the Next Steps. Before the Sen. Comm. on Health, Education, Labor and Pensions*, 109th Cong. (2003) (Statement of William Frist) [hereinafter Smallpox Hearings]

⁶⁸Donald A. Henderson, *Smallpox as a Biological Weapon: Medical and Public Health Management*, 281 JAMA 2127 (1999).

⁶⁹*Id.*

⁷⁰Steven Rosenthal et. al., *Developing New Smallpox Vaccines*, 7 EMERGING INFECTIOUS DISEASES 920, 920 (2001).

⁷¹Center for Disease Controls, *Smallpox Vaccine No Longer Available for Civilians*, 32 MORBIDITY AND MORTALITY WEEKLY REPORTS 387 (1983).

its personnel.⁷²

The smallpox vaccine does not use the variola virus that causes smallpox. Rather, the smallpox vaccine is a preparation of vaccinia virus, an Orthopoxvirus related to the variola virus.⁷³ Interestingly, the vaccinia virus is a descendent of the cowpox virus used by Jenner. The human manipulation of the cowpox virus created the new virus that was called the vaccinia virus.

The older production method used to produce Wyeth Dryvax was very primitive. In a process called “scarification”, the flank and abdomen of a calf (the “vaccinifer”) is scored in a grid pattern.⁷⁴ The seed vaccinia virus is rubbed into the scarified area and allowed to incubate for several days. After the incubation period, the skin has viral lesions that are removed by scraping the skin. These scrapings (the “vaccine pulp”) are then purified, dried, and reconstituted.

Health care workers administer the vaccine with a bifurcated needle dipped in the vaccine. The workers prick the subject five to fifteen times on the arm with the needle. An effective vaccination, or “take”, results in the formation of a pustular lesion at the vaccination site six to ten days after vaccination.⁷⁵ A scab forms and leaves a scar after approximately three weeks. The vaccine works by eliciting an immune response to the antigens of the vaccinia virus. These vaccinia antibodies also recognize variola because the viruses are closely related. The vaccine, therefore, allows the body to mount an immune response quickly against smallpox.⁷⁶ In fact, doctors recommend receiving a vaccine even after exposure to natural smallpox because the production of antibodies against the vaccinia vaccine is quicker than against natural smallpox.

⁷²Center for Disease Controls, *Vaccinia (Smallpox)Vaccine, Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 50 MORBIDITY AND MORTALITY WEEKLY REPORT (2001).

⁷³See Rosenthal et al., *supra* note 70, at 940. The vaccinia virus used for the vaccine has been passed through numerous generations of calves rendering the virus less virulent.

⁷⁴F. FENNER ET AL., *supra* note 31, at 280. Researchers chose this area of the calf because it is less susceptible to contamination from excretions.

⁷⁵Rosenthal et al., *supra* note 70, at 920.

⁷⁶F. FENNER ET AL., *supra* note 31, at 295. The nature of the immunity depended upon the amount of time since the vaccination. In the years immediately following vaccination, the body can mount a sufficient immune response to prevent any viral replication. An infection several years after vaccination may result in replication but no symptoms. After many years, however, the vaccination may have little effect and variola infection could lead to death. *Id* at 295.

This ability to confer immunity post-exposure is the reason that the U.S. wants ample supplies available. In fact, Secretary Thompson announced a goal to have enough vaccine stockpiled by the end of 2002 to vaccinate every U.S. citizen in the case of a smallpox attack. This supply of smallpox vaccine would be expected to come from several sources. First, the U.S. government has a stockpile of 15.4 million doses of the Wyeth Dryvax smallpox vaccine. While this vaccine is being used for the Vaccination Plan, there would still be some available for the general public in the case of an attack. Additionally, clinical studies by the NIH indicated the vaccine could be diluted one in five and still be effective. Second, the vaccine manufacturer Aventis Pasteur recently discovered a stockpile of 85 million doses of smallpox vaccine at a Pennsylvania production facility.⁷⁷ Even though Aventis produced the vaccine in 1958, studies show it is still effective.⁷⁸ The Aventis vaccine and Wyeth Dryvax were both produced by scarification but the Dryvax was freeze-dried whereas the Aventis is in liquid form.

The U.S. government also has a contract with the British biotechnology firm Acambis to supply 209 million doses of smallpox vaccine.⁷⁹ Whereas the Wyeth and Aventis vaccines were produced by scarification, Acambis produces the newer vaccine in cell culture. This method is cheaper, cleaner, and less likely to be contaminated. The U.S. government also has contracts with Acambis and Danish biotech firm Bavarian Nordic to conduct initial trials of a new smallpox vaccine that does not threaten immuno-compromised individuals.⁸⁰

D. Complications from the Smallpox Vaccine

⁷⁷See Melody Peterson, *A Nation Challenged: The Drug Makers; A New Batch of Old Smallpox Vaccine*, N.Y. TIMES, March 29, 2002, at A19.

⁷⁸See Robert Pear, *A Nation Challenged: The Bioterrorism Threat; Smallpox Vaccine is Still Potent, Officials Say*, N.Y. TIMES, March 30, 2002, at A8.

⁷⁹See Nic Hopkins, *U.S. Asks Acambis to do Smallpox Work*, THE TIMES (London), Feb. 26, 2003, at 27.

⁸⁰See *id.*

Even though the vaccine does not use the variola virus, it can still result in serious complications including skin infections, encephalopathy, and other unusual reactions. The following section lists the most common side effects observed from previous vaccinations.

1.

Eczema vaccinatum

Individuals with a history of eczema can develop eczema vaccinatum. Eczema is a common, hereditary autoimmune disorder characterized by patches of chronically red and irritated skin.⁸¹ When individuals who suffer from eczema receive the smallpox vaccine, they can develop lesions where they normally have eczema in addition to the lesion at the vaccination site.⁸² These eruptions can spread to healthy skin and are usually accompanied by high temperature and swollen lymph nodes. One estimate of the fatality rate for eczema vaccinatum is ten percent.⁸³

2.

Progressive Vaccinia

Progressive vaccinia occurs in individuals with comprised immune systems such as individuals with defective immunity, individuals taking immunosuppressive drugs, and individuals with AIDS.⁸⁴ With progressive vaccinia, the body is unable to mount an effective immune response against the vaccine. The vaccine site

⁸¹ See Donald A. Henderson et al., *Consensus Statement: Smallpox as a Biological Weapon: Medical and Public Health Management* 281 JAMA 2127, 2135 (1999).

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

does not heal and the eruptions soon spread.⁸⁵ The fatality rate for individuals with progressive vaccinia is up to seventy-five percent.⁸⁶

3.

Generalized vaccinia

Generalized vaccinia occurs in a small number of healthy individuals. With a routine vaccination, a lesion only develops at the vaccination site. However, individuals with generalized vaccinia develop lesions throughout their body. These individuals may experience high fever and discomfort though death is rare.⁸⁷ In one of the first reported adverse reactions during the Vaccination Plan, a Florida nurse suffered from generalized vaccinia. Press accounts characterized her reaction as vaccinia lesions covering her chest and back. Doctors are treating the nurse with antihistamines and are hopeful that she will recover without scarring.⁸⁸

4.

Accidental inoculation

Accidental inoculation occurs when the vaccinated individual transfers the vaccinia virus from the vaccination site to another part of her body or to another person. When smallpox vaccination occurred, this complication was the most common and least serious. The most common locations for transferal were the eyelids and the vulva. Recently, doctors hospitalized a woman in California with an eye infection resulting

⁸⁵F. FENNER ET AL. *supra* note 31, at 300.

⁸⁶Rosenthal et al., *supra* note 70 at 921.

⁸⁷Henderson et al., *supra* note 81 at 2135.

⁸⁸See Ceci Connolly, *Reactions May be Linked to Vaccine; 3 Workers Report Serious Side Effects*, WASH. POST, Feb. 28, 2003, at A8.

from contact with a vaccinated military personnel.⁸⁹

5.

Postvaccinial Encephalopathy and Encephalitis

Encephalopathy occurs in individuals younger than two years old. Severe symptoms, such as fever and convulsions, begin about a week after vaccination. Encephalopathy can be fatal and most individuals who suffered from it did not fully recover.⁹⁰ Postvaccinial Encephelitis generally occurred in individuals older than two years. It starts with fever, headache and vomiting. Individuals can become drowsy and disoriented. Additionally, they can suffer from convulsions and potentially slip into a coma. The mortality rate is approximately thirty-five percent.⁹¹

Conclusion

While the smallpox vaccine does not use the variola virus, it is still a risky vaccine. Approximately seven to nine individuals died every year during the U.S. smallpox vaccination program.⁹² The majority of these deaths were attributed to postvaccinial encephalopathy. It is not clear whether the current program would have a similar rate of side effects since the vaccine was primarily administered to children. On the other hand, a cause for concern is the incidental infection of immune compromised individuals such as AIDS patients and cancer patients receiving chemotherapy.

Part IV: Traditional Vaccine Liability and Existing Regimes

⁸⁹ See Lisa Richardson, *Infection Tied to Smallpox Vaccine; The Eye Problem is Linked to Contact with a Member of the Military Who was Inoculated*, L.A. TIMES, March 1, 2003, at M2.

⁹⁰ Henderson et al., *supra* note 81, at 2135.

⁹¹ *Id.*

⁹² Rosenthal et al., *supra* note 70, at 921.

Normally a person suffering an injury could bring a tort claim under a common law theory. Additionally, workers suffering injuries arising out of employment could receive workers' compensation. In order to better understand the current liability regime and its alternatives, the first section provides a brief survey of the history of products liability then summarizes the current doctrines. The next section provides an overview of workers' compensation and discusses its applicability to the President's vaccine program. Finally, the last section discusses the effect of HSA Section 304 on these compensation regimes.

A.

A Brief History of Products Liability

A historical view of products liability shows a shift from cabining liability to liberalizing recovery. Before the 1960's, there was little litigation against vaccine manufacturers. During this time, however, there was extensive development in the common law. As the modern products liability law began to develop, the number of claims against vaccine manufacturers dramatically increased. Currently there are several common law theories of liability for vaccine injuries including negligence, strict liability, breach of warranty, and failure of the duty to warn. Though HSA Section 304 limits the applicability of many of these theories, they are still useful to discuss. This section outlines these theories by recapitulating their historical development.

Early drug and vaccine cases were brought under negligence theories. As defined in a leading treatise, negligence claims have four elements: (1) a duty to a certain standard of conduct, (2) a breach of the duty, (3) a causal connection between the conduct and the injury, and (4) actual loss or damage suffered by another individual.⁹³ Though this theory of liability was available, early courts severely restricted its scope. This limitation resulted from the famous English case of *Winterbottom v. Wright* involving a defective

⁹³PROSSER AND KEETON ON TORTS 164-165 (West 5th Ed. 1984).

horse-drawn coach that injured the driver.⁹⁴ As a result of a chain of independent contractors, the plaintiff sued a company that did not hire him directly. The obscure facts of the case created the question whether the action was in tort or in contract. Counsel for defendant argued the defense of privity applied whether “the form in which the action is conceived be *ex contractu* or *ex delicto*.”⁹⁵ In finding for the defendant, the court noted that there was no privity between the driver and the contractor.⁹⁶ It is a notable case for several reasons. First, it is an early attempt to limit the scope of liability for defective products. Second, in attempting to limit the scope of liability, it had a lasting effect on products liability law by conflating the theories of tort and contract. In order for plaintiffs to bring a successful negligence claim, there must be privity of contract.

Despite this early privity requirement, some courts found exceptions.⁹⁷ Perhaps the most famous case was *Thomas v. Winchester* where the defendant sold an extract of the poison belladonna to another druggist in a jar labeled as dandelion extract.⁹⁸ In finding liability, the court noted that the defendant’s duty arose “out of the nature of his business, and the danger to others incident to its mismanagement.”⁹⁹

⁹⁴ *Winterbottom v. Wright*, 152 Eng. Rep. 402 (Ex. 1842). While these facts of *Winterbottom* are relatively simple, the relationship between the plaintiff and defendant is complicated. The defendant wanted coaches and drivers to deliver mail. He contracted with the Postmaster General to provide and repair the coaches. The defendant then contracted with a person named Atkinson to provide the horses and drivers. Atkinson hired the plaintiff to be a driver of a coach. So Atkinson hired the plaintiff to drive the Postmaster General’s coaches to deliver mail for the defendant. While the plaintiff was on his route, the coach broke and threw him to the ground.

⁹⁵ *Id.* at 405

⁹⁶ In his opinion, Baron Rolfe stated that “there is no point at which such action would stop. The only safe rule is to limit the right to recover to those who enter into the contract: if we go one step beyond that, there is no reason why we should not go fifty.” *Id.* At 405. Many commentators suggest that this case wrongly imported contract principles into the tort setting. Nevertheless, these same commentators note the pragmatism of the judges. In the background of the case, even in the mid-1800’s, there was significant concern about the liability exposure of manufacturers and distributors. In their opinions it was clear that the court imported the idea from contract to cabin liability

⁹⁷ Judge Sanborn summarized these exception in *Huset v. J.I. Case Threshing Machine Co.*: (1) negligence by the manufacturer or vender that was “imminently dangerous” and committed in the preparation of an article intended to “preserve destroy or effect human life”, (2) the owner’s act of negligence that causes injury to a person invited by the owner to use a defective appliance upon the owner’s property, and (3) sale of an article known to be dangerous to life or limb without notice of the qualities that causes reasonably anticipated injuries. *Huset v. J.I. Case Threshing Machine Co.*, 120 F. 865 (8th Cir. 1903).

⁹⁸ See *Thomas v. Winchester*, 6 N.Y. 397 (1852).

⁹⁹ *Id.* at 400.

At the start of the century, courts still operated within a liability regime requiring privity or an exception to the rule such as *Thomas v. Winchester*. Justice Cardozo's majority opinion in *MacPherson v. Buick Motor Co*¹⁰⁰ marked the end of this approach. In *MacPherson*, the court held that the principle of *Thomas v. Winchester* would not be confined to inherently destructive items such as poisons and explosives. Judge Cardozo reasoned that this category of dangerous items should include ordinary items that are rendered dangerous through negligence. If the manufacturer knows that persons other than the purchaser will use the item, then they are under a responsibility to make the item carefully. Other courts quickly followed this idea and the privity requirement soon disappeared.

Despite the disappearance of the privity requirement, plaintiffs still needed to prove negligence. For many cases this task was difficult. Academic legal literature discussed the possibility of holding manufacturers liable without fault to circumvent this problem and facilitate recovery. This doctrine, eventually called "strict liability" only required proof that the product caused the injury. The judicial acknowledgement of strict liability first appeared in the California Supreme Court case of *Escola v. Coca-Cola Bottling Company of Fresno*.¹⁰¹ The case involved a waitress injured by a Coke bottle that exploded while she was putting it in the restaurant's refrigerator. In his concurring opinion, Justice Traynor stated that "it should now be recognized that a manufacturer incurs an absolute liability when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injuries to human beings."¹⁰² In reaching this conclusion, Justice Traynor relied heavily on several policy arguments. First, he argued that "public policy demands that responsibility be fixed whenever it will most effectively reduce

¹⁰⁰ See *MacPherson v. Buick Motor Co.*, 217 N.Y. In the case, the plaintiff purchased a 1909 Buick from a dealer in Schenectady, N.Y. While driving his car at eight miles per hour, one of the wooden wheels broke and the car collapsed injuring McPherson. There was a privity problem because Buick purchased their tires from the Imperial Wheel Company.

¹⁰¹ *Escola v. Coca-Cola Bottling Co. of Fresno*, 150 P.2d 436 (Cal. 1944)

¹⁰² *Id.* at 440.

the hazards to life and health inherent in defective products that reach the market.”¹⁰³ This reasoning introduced the idea of assigning liability to the person who can take the cheapest measures to avoid the injury.¹⁰⁴ Second, he argued that “the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business.”¹⁰⁵ Almost twenty years later, in *Greenman v. Yuba Power Products*, the California Supreme Court adopted Justice Traynor’s theory of absolute liability.¹⁰⁶

Two years after *Greenman*, the American Law Institute promulgated the Restatement (Second) of Torts Section 402A. This section had a significant effect on products liability and still continues to have an effect. As an operative matter, it does not require negligence. Rather a manufacturer is liable under Section 402A if the plaintiff proves that: (1) the product was in an unreasonably dangerous and defective condition at the time of the injury, (2) the defendant supplied the product, (3) the defect caused the injury, and (4) the product was defective when it was sold.¹⁰⁷ Consistent with the evolution of the common law, Section 402A does not require privity. Though the language of Section 402A is potentially expansive, comment k carves out an exception for unavoidably unsafe products. The comment defines unavoidably unsafe products as “incapable of being made safe for their intended and ordinary use.”¹⁰⁸ If the product is properly prepared, marketed and labeled then there is no strict liability against the manufacturer of an unavoidably unsafe product.

Vaccines are the paradigmatic unavoidably unsafe product. In fact, comment k uses a vaccine example to illustrate the rule:

¹⁰³*Id.* at 441.

¹⁰⁴*See*, GUIDO CALABRESI, THE COST OF ACCIDENTS; A LEGAL AND ECONOMIC ANALYSIS (1970)

¹⁰⁵Escola, 150 P.2d at 441.

¹⁰⁶*Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897 (Cal. 1963) (holding that a manufacturer is “strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being”). *Id.* at 900.

¹⁰⁷Restatement (Second) of Torts §402A.

¹⁰⁸Restatement (Second) of Torts §402A, comment k.

An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

As a result, vaccine products liability cases frequently involve comment k issues.

Comment k says that strict liability does not apply to unavoidably unsafe products if they are properly prepared, marketed, and labeled. Additionally, comment j requires that the manufacturer give the user ample warning. The basis for liability is a combination of a comment k failure to properly label and a comment j requirement to give a user ample warning. The exact doctrinal underpinnings of these cases can be unclear. Some courts hold that the defendants were negligent in discharging their duty to warn. Others hold the defendants strictly liable for an unsafe product because they did not discharge their labeling duties under comment k to be an exempt unavoidably unsafe product. Some commentators suggest that the difference between the two inquiries is that negligence focuses on state of mind whereas strict liability focuses on the state of the product.¹⁰⁹

A significant amount of litigation surrounds the manufacturer's failure to warn about the risks of a vaccine. The origin of this theory of liability is a string of cases in the late 60's and early 70's. The first and most famous case is *Davis v. Wyeth Laboratories* where the court noted that the manufacturer had a duty to warn the public of the risks.¹¹⁰ The court reasoned that the failure to adequately warn the public created an "unreasonably dangerous" product and the defendant was strictly liable for any resulting injuries. While a warning by the prescribing doctor would ordinarily suffice, the court held that the mass immunization context placed a greater burden on the manufacturer to supply the information.

¹⁰⁹David G. Owen et al., *Madden & Owen on Products Liability*, §9:3.

¹¹⁰*See Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).

This case opened the door for other plaintiffs to bring claims against vaccine manufacturers. In another watershed case, *Reyes v. Wyeth Laboratories*, the Fifth Circuit liberalized recovery by lowering the burden of proof for causation. In this case, an infant contracted polio two weeks after receiving the polio vaccine. The court ruled that the manufacturer failed to warn the plaintiff of alternative vaccines. As a result, the court held that the vaccine was unreasonably dangerous because it did not provide adequate warnings.¹¹¹ Additionally, the court created a rebuttable presumption that a consumer warned of the risks will act to properly minimize her risks. In applying the rebuttable presumption, however, the court did not consider that there was an epidemic outbreak of polio in the neighborhood. These facts combined with the holding virtually eliminated the requirement of causation.

As a result of the *Davis* and *Reyes* decisions, vaccine manufacturers had several duties. First, they must ensure that vaccinees are informed of the risk. The information can come from the doctor acting as a learned intermediary or it must come from the manufacturer. Second, the information must adequately describe the risks. These requirements are very amorphous and led to increasing recoveries throughout the early 1980's until passage of the NCVIA. The NCVIA, however, does not cover the smallpox vaccine. Absent HSA Section 304, plaintiffs could bring a duty to warn case against smallpox vaccine manufacturers. Though these claims would not always be successful, they would provide some individuals an avenue to receive compensation.

While breach of the duty to warn has been the most successful theory of recovery, plaintiffs could bring other theories for recovery. Plaintiffs could bring a negligence claim. Though courts no longer require privity, recovery under this theory is difficult for several reasons. First, many vaccine injuries are not the result of negligent conduct rather they are an unavoidable side effect. Second, even if there was negligence, it can be difficult to obtain information proving the manufacturer was negligent.

Plaintiffs could also bring a claim for breach of warranty. This theory relies on the intermingling of contract

¹¹¹In reaching this holding the court rejected the argument of the American Academy of Pediatrics in their amicus brief that the mandatory vaccination laws obviated the need for warnings.

and tort theories present in *Winterbottom v. Wright*. The warranty can be either express or implied and the plaintiff only needs to show that the product does not comply with the warranty. There is no requirement to prove negligence.

Another possibility is a manufacturing defect claim. As a general rule, there are very few manufacturing defect cases because the FDA exercises substantial oversight over vaccine production so there are few errors.

¹¹² Perhaps the most famous was the Cutter litigation during the late 50's and early 60's. These cases resulted from the accidental distribution of polio vaccine containing a live, virulent strain.¹¹³ If a vaccine injury did result from a deviation from best manufacturing practices then this theory would be available. On the whole, however, there are very few manufacturer defect cases.

On the other hand, there has been more design defect claims particularly when another manufacturer produces a different vaccine.¹¹⁴ Absent HSA Section 304, there may have been some claims under this theory because of the availability of a different manufacturing technique. Individuals in the Vaccination Program will receive Wyeth Dryvax, which is produced by scarification. Though it is in limited supply, the Acambis vaccine is produced using cell culture techniques. It is foreseeable that injured parties could claim that a manufacturer should have produced the vaccine by cell culture. On the other hand, manufacturers might have a strong defense that they produced the older vaccine over thirty years ago before the availability of cell culture techniques.

In conclusion, there are various theories of liability available at common law. Historically, breach of the duty to warn has been the most common and successful. Nevertheless, there are other theories available. While some plaintiffs would not be successful, tort claims provide the opportunity for compensation. As seen in Section C *infra*, HSA Section 304 removes the availability of many of these theories.

¹¹²See MATTHEW BENDER'S PRODUCTS LIABILITY at §51.05(1)

¹¹³See Note, *The Cutter Polio Vaccine Incident*, 65 Yale L.J. 262 (1955).

¹¹⁴See *Toner v. Lederle Laboratories*, 732 P.2d 297 (Idaho 1987) (holding the manufacturer liable for a defective design because a competitor developed a safer vaccine).

B.

Worker's Compensation

President Bush's vaccine proposal outlines certain first responders who will be eligible for the smallpox vaccine. These individuals were chosen because their jobs place them on the front lines responding to biological attack. As a result, it would seem sensible that first responders injured from the vaccine could receive workers' compensation. While this conclusion is common sense to some individuals, the availability of workers' compensation has been a source of great uncertainty.

Worker's compensation is a government-mandated mechanism to compensate workers for work-related injuries.¹¹⁵ The substantive contours of a workers' compensation program vary by state. Additionally, federal employees receive workers' compensation under the Federal Employees Compensation Act (FECA) administered by the Department of Labor. Nevertheless, there are some typical provisions in most statutes and regulations.

First, employees generally are entitled to benefits for any injury resulting from an accident that "arises out of and in the course of employment."¹¹⁶ Second, the negligence or fault of the employer or employee does not matter. Third, benefits are usually limited to employees rather than independent contractors. Finally, the employee normally waives her right to sue the employer for damages for an injury covered by the act. Usually, the employer must secure their workers' compensation liability through private insurance, state-fund

¹¹⁵LARSON'S WORKERS' COMPENSATION LAW §1.01

¹¹⁶*Id.*

insurance, or self-insurance.¹¹⁷

As a key conceptual point for discussing the appropriate compensation regime, it is important to differentiate strict liability in tort and workers' compensation. An obvious distinction is who bears the cost. As a first cut, the manufacturer bears the cost in a strict liability claim and the employer bears the cost in a workers' compensation claim. Presumably, both individuals can spread these costs with their other costs of business. A manufacturer would spread the cost to other individuals who purchase his goods while the employer spreads the costs to the purchasers of his goods or services.

There is a subtler difference. Both strict liability and workers' compensation do not require fault meaning that there can still be recovery for injuries caused by non-negligent conduct. In a claim for damages under strict liability, the person must prove that the vaccine caused the injury. In a workers' compensation claim, however, the claimant must only show that the injury arose from the course of employment.¹¹⁸ Additionally, there are no defenses in a workers' compensation claim whereas strict liability tort claims offer several affirmative defenses such as contributory negligence or act of god.

So the outcome of a strict liability claim largely turns on whether the injury "arises from employment." This is an area of workers' compensation where states take different approaches. There are currently three major methods: (1) the increased risk test—the claimant must show that the nature of the work exposed her to a higher risk of injury than the normal population, (2) the actual risk test—the claimant must show

¹¹⁷*Id.*

¹¹⁸Perhaps a stylized example would illustrate the point. Suppose a person works at a warehouse putting boxes on shelves. One day, rather than using a ladder they stand on a box to reach the top shelf. In the process of putting a box on the shelf, they fall and injure their back. A strict liability claim requires the employee to prove the boxes caused his injury. Presumably, this inquiry would ask whether it was foreseeable that a person would use the box as a step.

that the nature of the work exposed her to risk regardless of the level of risk in the population, and (3) positional risk test—the claimant must show that the injury would not have occurred but for the conditions or obligations of the employment.¹¹⁹ There is a question whether the vaccination program “arises from employment” regardless of the test a state adopts because the Vaccination Plan is voluntary. The Federal and state governments are only beginning to answer these questions.

At the Federal level, the Department of Labor’s Office of Workers’ Compensation Plans (the “OWCP”) announced the availability of workers’ compensation for smallpox vaccine injuries.¹²⁰ In order to receive compensation under FECA, a claimant must meet five requirements: (1) the claimant must file the claim within three years of the injury, (2) the claimant must be a civil employee, (3) the injury must have resulted from the incident claimed, (4) the injury must occur within the performance of duties, and (5) the injury must be causally related to factors of employment.¹²¹ Additionally, the OWCP announcement instructs claimants to provide medical evidence of the injury.¹²² While FECA provides compensation for injuries from the vaccine, it does not compensate for voluntary absences from work. This distinction is important because some first responders have taken days off work to avoid infecting co-workers or patients. Under these rules, FECA would not provide compensation for these absences.

In the case of secondary transmissions, FECA provides some coverage of the secondarily infected individual. The announcement suggested that compensation may be available to unvaccinated workers who contract vaccinia from a vaccinated co-worker. By omission this statement implies that some co-workers will be unable to receive compensation. It also implies that non-Federal employees will be unable to recover for injuries resulting from secondary transmissions from Federal employees.

¹¹⁹*Id.*

¹²⁰Department of Labor Office of Workers’ Compensation, *OWCP Guidance on Coverage for Smallpox Inoculations*, (available at http://www.dol.gov/esa/regs/compliance/owcp/dfec_smallpox_policy.htm) [hereinafter OWCP Guidance]

¹²¹Department of Labor Office of Workers’ Compensation, General Provisions of the FECA (available at http://nt5.scbbs.com/cgi-bin/om.isapi.dll?clientID=469704&infobase=feca-pt2.nfo&jump=2-0200&softpage=PL_frame#JUMPDEST.2-0200).

¹²²OWCP Guidance, *supra* note 120.

The availability of workers' compensation under state law is less clear. Generally, states fall into two categories. First, some states explicitly cover vaccine injuries. In hearings before the Senate Subcommittee on Health, CDC Director Julie Gerberding testified that thirty-three states offer some coverage through workers' compensation.¹²³ For example, following President Bush's public announcement in December, Ohio quickly announced that the state's workers compensation would cover vaccine-related injuries. Ohio's Better Worker's Compensation ("BWC") program covers injuries when (1) side effects are more severe than normal, (2) health care workers advise the individual to seek medical attention, or (3) illness causes the worker to miss more than seven days of work.¹²⁴ The program covers the cost of care and lost wages if the worker misses more than seven days.¹²⁵ Even though Ohio will compensate smallpox vaccine injuries, they have decreased their estimates of demand for the vaccine.¹²⁶ Other states only offer partial coverage under their workers' compensation though many are working to provide comprehensive coverage.

Some states are currently uncertain whether their workers' compensation covers vaccine injuries. For example, the State of Wisconsin's website has an FAQ stating that "[a]ny compensation must come through worker's compensation. DHFS is investigating what exactly is and is not covered by Wisconsin's worker's compensation in regard to pre-event vaccination."¹²⁷ There are several potential reasons for this ambiguity. First, some states are actively working to develop a compensation program. For example, state legislators in Utah are currently trying to design a bill that allows workers to recoup medical expenses and lost wages.¹²⁸ Second, some states are still trying to understand the application of their laws. Finally, one state has indi-

¹²³Smallpox Hearings, *supra* note 67 (testimony of Dr. Julie Gerberding, Director, CDC)

¹²⁴Ohio Better Workers' Compensation, Fact Sheet: Workers's Compensation Benefits for the Smallpox Vaccine (available at <http://www.ohiobwc.com/downloads/brochureware/factsheets/PoxFactsheet.pdf>).

¹²⁵If the worker misses between seven and fourteen days, they are only allowed to recover lost wages for the number of days missed beyond the seventh day. On the other hand, if the worker misses more than fourteen days, they can recover the wages for the total number of days missed.

¹²⁶Ferdinand & Connolly, *supra* note 20, at A12.

¹²⁷Wisconsin Medical Society, Frequently Asked Questions about Pre-Event Smallpox Vaccination Plans available at http://www.wisconsinmedicalsociety.org/physician_resources/bioterrorism/dhfs_smallpox_faq.cfm (last visited on January 29, 2003).

¹²⁸Noreen Gillespie, *Slow Start to Smallpox Vaccines*, THE DESERT NEWS, Jan. 25, 2003, at A2.

cated it will not cover the cost of medial treatment and lost income.¹²⁹

In conclusion, federal employees can recover workers' compensation for vaccine injuries but not for preventative reasons. Additionally, unvaccinated workers may be able to recover for secondary transmissions from co-workers. At the state level, some states provide compensation, some states are uncertain and one state does not provide compensation. As a result, workers' compensation provides incomplete and variable compensation for vaccine injuries.

C.

The Homeland Security Act

Shortly after the attacks on September 11, President Bush created an Office of Homeland Security to coordinate the anti-terror campaign with other federal agencies.¹³⁰ After formation of the non-cabinet level office, a dispute between Congress and the White House erupted over the Head of Homeland Security's accountability to Congress.¹³¹ The White House position was that Mr. Ridge, the Head of Homeland Security, was a presidential advisor who has no obligation to testify before Congress.¹³² Under increasing pressure, however, President Bush proposed the creation of a Department of Homeland Security on June 6.¹³³ On June 24, the House introduced the Homeland Security Act of 2002. The centerpiece of the legislation was the merging of 22 government agencies into the cabinet-level department. The bill also contained other provisions including the smallpox provision, HSA Section 304.

¹²⁹ See Smallpox Hearings, *supra* note 67 (testimony of Dr. Julie Gerberding, Director, CDC).

¹³⁰ See Elizabeth Becker and Elaine Sciolino, *A Nation Challenged: Homeland Security; A New Federal Office Opens Amid Concern that Its Head Won't Have Enough Power*, N.Y. TIMES, Oct. 8, 2001, at B11.

¹³¹ See Elizabeth Becker, *A Nation Challenged: Domestic Security; Bush is Said to Clear a New Security Department*, N.Y. TIMES, April 11, 2001, at A16.

¹³² See Elizabeth Becker, *A Nation Challenged: Big Visions for Security Post Shrink Amid Political Drama*, N.Y. TIMES, May 3, 2002, at A1.

¹³³ See Elisabeth Bumiller and David E. Sanger, *Traces of Terror: The President; Bush as Terror Inquiry Swirls, Seeks Cabinet Post on Security*, N.Y. TIMES, June 7, 2002, at A1.

HSA Section 304 gives the Secretary of HHS authority to issue a declaration that an emergency requires the “administration of a covered countermeasure to a category or categories of individuals.”¹³⁴ The statute also gives the Secretary the authority to define the covered countermeasures and the effective time period of such measures.¹³⁵

HSA Section 304 shields vaccine manufacturers from traditional tort claims brought by individuals receiving the smallpox vaccine. The statute operates by deeming “covered persons” to be employees of the Public Health Services (the “PHS”).¹³⁶ The statute defines several “covered persons”: (1) vaccine manufacturers and distributors,¹³⁷ (2) the health care entities that provided the facilities,¹³⁸ (3) the licensed health care worker or other worker who is authorized to administer the vaccine¹³⁹ and (4) any agent or employee of the enumerated parties.¹⁴⁰ Under the Public Health Services Act (the “PHSA”), individuals must file a claim against the United States for injuries caused by an employee of the PHS when acting within the scope of employment.¹⁴¹

As a result, under the HSA, injured parties cannot bring claims against any of these groups in either state or federal court. A plaintiff’s only recourse is to bring a claim against the United States. Under the PHSA, these claims must be brought under the Federal Torts Claim Act (the “FTCA”), which only allows recovery upon the showing of negligent or wrongful conduct.¹⁴² As a result, vaccine recipients who suffer adverse reactions from the smallpox vaccine will receive compensation only if they prove negligence.

¹³⁴42 U.S.C. §233(p)(2)(A)(i).

¹³⁵42 U.S.C. §233(p)(2)(A)(ii) - (iii).

¹³⁶42 U.S.C. §233(p)(1).

¹³⁷42 U.S.C. §233(p)(7)(B)(i).

¹³⁸42 U.S.C. §233(p)(7)(B)(ii).

¹³⁹42 U.S.C. §233(p)(7)(B)(iii) and (7)(C).

¹⁴⁰42 U.S.C. §233(p)(7)(B)(iv).

¹⁴¹42 U.S.C. §233(a).

¹⁴²28 U.S.C. §1346(a). Before the passage of the FTCA, the doctrine of sovereign immunity did not allow lawsuits against the United States. The justification stems from early law that it would undermine the sovereignty of the king to permit suits in his own court. Restatement (Second) of Torts, ch. 45A, at 394 (1979). The purpose of the Act is to provide compensation when the conduct of government actors falls below socially acceptable levels. *See generally* Hughes v. U.S., 116 F. Supp. 2d 1145, (N.D. Cal. 2000).

Finally, the United States is only liable if: (1) a qualified person administered the vaccine,¹⁴³ (2) for an acceptable purpose,¹⁴⁴ (3) during the effective period declared by the Secretary,¹⁴⁵ (4) to an individual covered by the Secretary's declaration or reasonably believed to be covered.¹⁴⁶ As a result, the statute carefully proscribes recovery for individuals who are not deemed by the Secretary to require vaccination.

There are several additional wrinkles. First, the statute requires the covered person to cooperate with the United States in defending the case.¹⁴⁷ The statutory protections are not available to the covered person who fails to cooperate.¹⁴⁸ Additionally, the United States can recover any damages paid and litigation costs from a covered person who acted with gross negligence, recklessness or illegally.¹⁴⁹

On the other hand, the statute does cover some individuals who were not vaccinated but were infected by a vaccinated individual. There is a rebuttable presumption that the unintended party contracted vaccinia from a vaccine recipient if one of three circumstances are met: (1) the individual contracts vaccinia during the effective period of the declaration,¹⁵⁰ (2) the individual contracts vaccinia within thirty days of the effective period,¹⁵¹ or (3) the individual resides or has resided with a qualified person and contracted vaccinia.¹⁵²

In his January 24 declaration, Secretary Thompson used his authority to extend the parameters of the vaccine program. According to an aid of Secretary Thompson, the declaration tries to provide the widest possible protection from liability.¹⁵³ It achieves these ends by providing broad definitions to the statutory language.

There are three covered countermeasures: (1) the vaccinia vaccine,¹⁵⁴ (2) cidofovir and its derivatives,¹⁵⁵

¹⁴³42 U.S.C. §233(p)(2)(B)(i).

¹⁴⁴*Id.*

¹⁴⁵*Id.*

¹⁴⁶42 U.S.C. §233(p)(2)(B)(ii)(I)-(II).

¹⁴⁷42 U.S.C. §233(p)(5)(A).

¹⁴⁸42 U.S.C. §233(p)(5)(B)(i) - (iii).

¹⁴⁹42 U.S.C. §233(p)(6)(A).

¹⁵⁰42 U.S.C. §233(p)(2)(c)(ii)(I).

¹⁵¹42 U.S.C. §233(p)(2)(c)(ii)(I).

¹⁵²42 U.S.C. §233(p)(2)(c)(ii)(II).

¹⁵³Laura Meckler, *Laws Protect Those With Smallpox Vaccine*, N.Y. NEWDAY, Jan. 14, 2002, at A6.

¹⁵⁴Declaration Regarding Administration of Smallpox Countermeasures, 68 Fed. Reg. at 4212.

¹⁵⁵*Id.* Cidofovir is an antiviral drug that has shown promise in treating individuals with smallpox. HDP-CDV is a derivative of cidofovir that stops replication of the variola virus.

and (3) vaccinia immune globulin.¹⁵⁶ As a result, the statute will only exempt liability for the administration of these compounds. There are several classes of qualified persons: (1) a member of a state or local smallpox response team, (2) public safety officers such as police officers, firefighters, and emergency medical technicians, (3) certain overseas personnel.¹⁵⁷ Additionally, Secretary Thompson broadened the definition of “administration of covered countermeasure” to include ancillary support including education, screening and monitoring.¹⁵⁸ The effective date runs from January 24, 2003 to January 24, 2004.¹⁵⁹

While HSA Section 304 limits the liability of covered entities for adverse reactions, it does not foreclose the recovery of workers’ compensation. HSA Section 304 forbids alternate state or federal claims within the scope of the statute.¹⁶⁰ This prevents potential victims from bringing traditional tort claims. Nevertheless, workers’ compensation is not within the the preemptive sweep of HSA Section 304. As a result, injured parties have the option of filing negligence claims under HSA Section 304 or filing for workers’ compensation if it is available.

HSA Section 304 and Secretary Thompson’s declaration have several effects. First, providers are reluctant to vaccinate the general public because they are not “qualified persons.” Any adverse reaction would expose the provider to potential liability. Indeed, the delay in vaccinating first responders between President Bush’s announcement and Secretary Thompson’s declaration was caused by the fear of an adverse event before there was statutory protection. The second point is the breadth of HSA Section 304’s coverage. Secretary Thompson’s declaration covers many activities besides inoculation and many items besides the vaccinia vaccine. In conclusion, it is clear that the statute seeks to create an air-tight exemption when the provider administers the vaccine within the statutory framework.

¹⁵⁶ *Id.*

¹⁵⁷ Declaration Regarding Administration of Smallpox Countermeasures, 68 Fed. Reg. at 4212.

¹⁵⁸ *Id.* at 4213.

¹⁵⁹ *Id.*

¹⁶⁰ 42 U.S.C. §233(p)(3).

D.

Conclusion

The current regimes create a patchwork that provides compensation for some injuries but not others. The first mechanism of compensation is the tort system. In the absence of HSA Section 304, injured parties could bring common law tort claims against vaccine manufacturers and providers. Traditional theories of liability would include negligence, strict liability, failure of the duty to warn, and breach of warranty. Some of these theories would provide recovery without the need to prove negligence. HSA Section 304, however, exempts covered manufacturers and providers from liability. Plaintiffs can only bring a claim against the United States under the FTCA, which requires a showing of negligence. Those injured parties who would have successful claims under traditional non-negligence theories would not be able to recover under HSA Section 304.

Nevertheless, injured parties may be able to recover workers' compensation—the second mechanism of compensation. Workers' compensation may be available under state or federal law. Employees of the federal government can receive workers' compensation for vaccine injuries. Additionally, federal employees secondarily infected by co-workers may also receive compensation. The availability of workers' compensation for non-federal employees depends on state law. After the announcement of the vaccine program, states scrambled to understand the coverage of their workers' compensation programs. Currently, thirty-three states offer some compensation for vaccine injuries. Additionally, sixteen states are still undecided and one state is not providing compensation.

While workers' compensation provides a safety net for compensation, its coverage is incomplete for several reasons. First, the scope of compensation coverage is vague. While some states have made their compensation criteria available, other states have only indicated that compensation will be available to some individuals.

Additionally, the federal government and many states do not compensate for all secondary transmissions. If a policy goal is comprehensive compensation for vaccine injuries, then the current system clearly falls short. The next four parts of this article discuss ways to implement a comprehensive system.

Part IV: The Swine Flu Act

A common complaint of HSA Section 304 is the need to prove negligence to receive compensation. Doctrinally, this provision eliminates some common law tort remedies by turning back the clock to a time between *MacPherson* and the Restatement (Second) of Torts. Practically, it forecloses compensation for individuals who suffer adverse reaction from a vaccine that was properly manufactured. An alternative regime could shield manufacturers from liability but allow traditional common law tort claims against the United States. The approach would allow the same recovery that is available under the common law without exposing manufacturers to excessive litigation.

In a program to vaccinate the U.S. population against an anticipated outbreak of an especially virulent form of the flu, Congress passed the Swine Flu Act that adopted a similar liability scheme. These liability provisions are historically important because adverse reactions to the vaccine created extensive litigation until the mid-80's. This section analyzes the Swine Flu Act and draws lessons from its application. The first part of the section provides the historical context of the act. While the second part outlines the statutory operation, the third part discusses its application in litigation. Finally, the fourth part draws lessons from the Swine Flu Act that are applicable to forming a current regime.

A.

Background

In early January 1976, many Army recruits at Fort Dix suffered serious respiratory ailments. In fact, the Army hospitalized several recruits and one recruit died after an overnight hike in the January cold. Responding to the outbreak, Army doctors sent cultures to the New Jersey state lab with the results indicating the presence of common influenza virus. Four samples, however, revealed the presence of the swine flu virus.¹⁶¹

This result alarmed Army doctors because the swine flu virus caused the Influenza Pandemic of 1918. Perhaps the most virulent disease in modern times, the Influenza Pandemic of 1918 killed more than 20 million people worldwide including over 500,000 people from the United States.¹⁶² Individuals either died from bacterial pneumonia or other complications. Though the availability of antibiotics would have reduced the mortality rate from an outbreak in 1976, swine flu could still have been devastating.¹⁶³ Doctors had not seen this strain of the flu in humans since a decade after the epidemic. As a result, only older individuals have natural immunities from previous exposure.¹⁶⁴ Additionally, the swine flu's devastating effects on young, healthy individuals in 1918 compounded the potential problem.¹⁶⁵

Naturally the doctors at Fort Dix alerted the CDC of their findings. The CDC held a press conference on February 19 to preempt any leaks but the New York Times ran front-page article the next day announcing the return of the most lethal virus of modern medicine.¹⁶⁶ The CDC presented their findings to ACIP. On March 13, ACIP finalized a memorandum of possible approaches to the problem.¹⁶⁷ The first approach was

¹⁶¹RICHARD E. NEUSTADT & HARVEY V. FINEBERG, *THE SWINE FLU AFFAIR; DECISION MAKING ON A SLIPPERY SLOPE* (1980).

¹⁶²*Id.*

¹⁶³*Id.*

¹⁶⁴*Id.*

¹⁶⁵*Id.*

¹⁶⁶Harold Schmeck, *U.S. Calls Flu Alert on Possible Return of Epidemic Virus*, N.Y. TIMES, Feb. 20, 1976, at A1.

¹⁶⁷Memorandum from the Assistant Secretary of the Department of Health, Education and Welfare to James F. Dickinson (March 18, 1976). (on file with author).

to do nothing. The committee listed the potential action by the private industry and the possibility of no pandemic as benefits to this approach.¹⁶⁸ On the other hand, ACIP noted that action would be expected and that Congress would act in the absence of CDC action.¹⁶⁹

The second approach was phrased the “minimum response” approach.¹⁷⁰ This would entail the federal government advising the private drug industry and starting a public awareness campaign. The benefit of the approach was that it was a high visibility and low effort endeavor that would be relatively inexpensive. The drawbacks were two-fold. First, there was the concern that the private drug industry would not have the proper incentives to respond. Second, there was a concern that the vaccine would not reach certain segments of the population such as the poor, the near poor, and the elderly.

The third approach was called the “Government Program” approach.¹⁷¹ In this approach, the Federal government would advise vaccine manufacturers to start full scale production of 200 million doses of vaccine. The CDC would purchase the vaccine from the manufacturers and distribute the vaccine to the State Health Departments. The State Health Departments would try to immunize one hundred percent of the population. Additionally, the federal government would conduct extensive outreach programs to increase awareness. The advantages of the approach was that there would be maximum production of vaccine and the most equitable distribution throughout the population. Additionally, it would assure uniform distribution while still allowing the states to perform a typical state function. The drawbacks were that the system would be costly, inefficient, and may not work as intended.

The final approach was called the “Combined Approach.”¹⁷² The federal government would advise the vaccine manufacturers to make 200 million doses available to the states. In turn, state officials would develop

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

plans to immunize people in their states with the federal government would provide outreach and educational programs. This program offered many of the Government Program advantages but increased the state involvement. At the end of their memorandum, ACIP recommended this approach to the immunization program.

On March 24, President Ford convened a panel of experts to discuss the possibility of a vaccine program. Both Jonas Salk and Albert Sabin were present at the meeting. By several accounts, everyone voted for the vaccination program though several participants later expressed reservations.¹⁷³ Concerned about leaks to the press, Ford announced the vaccination plans immediately following the meeting. Within one month, Congress responded by adding the program to a pending appropriations bill.

While manufacturers began producing the vaccine, the issue of liability threatened to delay the whole process. In late May, one manufacturer ended negotiations with the government when they were unable to receive indemnification for any legal costs resulting from the program.¹⁷⁴ Following the Reyes decision in 1974, liability exposure increasingly concerned vaccine manufacturers. In addition to the cost of any awards, the cost of defending all lawsuits concerned the manufacturers' insurers. In early April, Merck's primary insurer informed the company that coverage for the swine flu was not possible.¹⁷⁵

The vaccine manufacturers met some resistance from Congress.¹⁷⁶ It was the beginning of August and there were no additional reports of the Swine Flu. With no signs of a pending epidemic, some members of Congress questioned the wisdom of the program. However, an outbreak of a new respiratory illness in Pennsylvania accelerated the passage of legislation and the inoculations started on October 1, 1976.¹⁷⁷

¹⁷³NEUSTADT & FINEBERG, *supra* note 161

¹⁷⁴*Id.* at 48.

¹⁷⁵*Id.* at 54.

¹⁷⁶*See, e.g.*, House of Representatives, Committee on Interstate and Foreign Commerce, Subcommittee on Health and Environment, *Supplemental Hearings*, 94th Congress, 2nd Session, Serial No. 94-113, June 28, 1976, p. 19. For example, Representative Henry Waxman stated "...the insurance industry is not acting responsibly when they are asking to charge three or four times the usual rate for a vaccine that does not offer significant risk, while at the same time they are insuring vaccination programs where there are more substantial risks involved." *Id.* at 19,

¹⁷⁷These cases were at the American Legion State Convention resulting in the name Legionnaire's Disease. NEUSTADT & FINEBERG, *supra* note 161

As part of the vaccination program, the CDC monitored the public health. By early December, it was clear that there was an elevated risk of Guillain-Barr Syndrome (GBS) in vaccinated individuals.¹⁷⁸ GBS is a paralytic disease caused by the immune system attacking peripheral nerves. In acute cases, it has a 25% mortality rate. On December 16, 1976, the program was terminated after the inoculation of over forty million people. Just three months after Congress established a liability system for vaccine injuries, it was clear that the provisions were going to be used.

B.

Statutory Operation

Congress identified three purposes when they passed the Swine Flu Act: (1) to protect individuals who manufacture, distribute, or administer the swine flu vaccine for liability other than their negligence (2) to establish an orderly procedure for claims arising from injury or death and (3) to meet any potential emergency by establishing a permanent approach to handling claims.¹⁷⁹

The Swine Flu Act operated in two ways. First, it exempted participating parties from tort claims. The statute deemed manufacturers, distributors, health care entities and health care professional meeting certain criteria to be participating parties.¹⁸⁰ The Swine Flu Act was the exclusive remedy against parties deemed “program participants” so that the Act also preempted any state cause of action.¹⁸¹ Second the statute allowed an individual to bring a claim against the United States under the FTCA using traditional common

¹⁷⁸During the surveillance time, there were fifty-eight deaths. Additionally, there were over two hundred adverse reactions attributable to the disease. Overall, the risk of an adverse reaction was estimated at one in 100,000 vaccinations. *Id.*

¹⁷⁹*Id.*

¹⁸⁰National Swine Flu Immunization Program of 1976, Pub L. No. 94-380, 90 Stat. 1113 (1976). [hereinafter Swine Flu Act]

¹⁸¹Program participants are the manufacturers, distributors, organization providing inoculation, and health care workers. The organizations must not charge for the vaccine and must comply with an informed consent form and a procedures form. The health care workers must also comply with the informed consent form. *Id.*

law theories such as negligence, strict liability, or breach of warranty.¹⁸² This provision relaxed the mens rea requirement of a traditional FTCA cause of action. When an individual brought a claim, the law of the location of the act or omission governed the choice of law.¹⁸³ Further, claims would only be adjudicated in federal court because the statute mandated removal of state claims to federal court.

The statute charged the Attorney General with defending any claims. It also created an incentive for program participants to assist the Attorney General. In order to remain a program participant, the party must cooperate with the United States in defending against the claim. Finally, the United States had a right of contribution against any program participant who acted negligently. This right allowed the United States to receive compensation for the damages paid to injury victims.

C.

Results

By early 1977, there were many claims against the United States under the Swine Flu Act. The Judicial Panel on Multi-District Litigation (JPML) ordered the litigation to be consolidated for pre-trial discovery in the D.C. Circuit.¹⁸⁴ On June 20, 1978, the Secretary of the Department of Health, Education and Welfare stated that plaintiffs did not need to prove negligence in order to recover under the Swine Flu Program. Rather, plaintiffs only needed to show that they developed GBS as a result of the swine flu vaccination and suffered the alleged damages.¹⁸⁵

Aside from GBS, there were reports of other side effects believed to be caused by the vaccine. By only applying the policy to GBS, the Secretary's announcement created several tiers of litigation. For individuals

¹⁸²Swine Flu Act, *supra* note 180.

¹⁸³*Id.*

¹⁸⁴*See In re Swine Flu Immunization Products Liability Litigation*, 446 F.Supp. 244 (JPML) (upholding the order to consolidate discovery in the District of the District of Columbia).

¹⁸⁵*See In re Swine Flu Immunization Products Liability Litigation*, 464 F.Supp. 949 (JPML)

suffering GBS, it was easier to recover damages. The government established an approach of settling some cases and fighting others. Individuals experiencing the onset of GBS within five weeks of vaccination were virtually guaranteed recovery.¹⁸⁶ Similarly, onset within ten weeks also had a high chance of recovery. The other tier of litigants was individuals who did not suffer GBS but suffered other diseases. The Secretary's declaration did not apply to them. Instead they needed to rely on common law doctrines to recover damages. Some plaintiffs were able to recover by presenting evidence showing that their illness was within the "family" of GBS.¹⁸⁷ Other courts held that some conditions were reasonably foreseeable and that the generic warnings by the United States failed to disclose these conditions. Some courts permitted recovery under a negligence theory for the government's failure to exercise reasonable care in providing the warnings.¹⁸⁸ Other courts found that the inadequate warnings rendered the products unreasonably dangerous resulting in strict liability.¹⁸⁹ Though there were some successes, many cases that went to trial resulted in no recovery. Many of these cases involved conditions less clearly associated with the swine flu vaccine. On the other hand, some courts denied recovery for failure to warn of conditions that other courts found material.¹⁹⁰ In the end, the Swine Flu Act litigation was very long and costly.

D.

Conclusion

Clearly, the Swine Flu Act allowed more recovery than HSA Section 304. While the more expansive scope

¹⁸⁶Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. Envtl. Aff. L. Rev. 169, 184 (1986).

¹⁸⁷*See Unthank v. U.S.*, 732 F.2d 1517 (10th Cir. 1984) (holding the United States liable for injuries caused by transverse myelitis because it fell in the broader category of GBS).

¹⁸⁸*See Gassman v. U.S.*, 589 F. Supp. 1534 (M.D. Fla. 1984) (holding the United States liable for negligently failing to mention the risk of neurological injuries resulting from the vaccine).

¹⁸⁹*See Petty v. U.S.*, 740 F.2d 1428 (8th Cir. 1984) (holding the United States derivatively liable under a strict liability theory for an unreasonably dangerous product).

¹⁹⁰*See Saxe v. U.S.*, 577 F. Supp. 135 (N.D. Ohio 1983) (finding no duty to disclose information about contracting neurological disorders because they rarely occurred in the general population).

made recovery easier, it did not eliminate every impediment to recovery. As some of the cases highlight, the most difficult hurdle for plaintiffs to clear was proving causation. Certainly, the Secretary's announcement that recovery would be available for individuals suffering from GBS made recovery easier for these individuals. More specifically, the government's temporal test for causation assured a quick settlement. For cases that did not settle, litigation was protracted, expensive and uncertain.

Part V: The National Childhood Vaccine Act

In products liability cases involving drugs or vaccines, causation is often the most difficult aspect. It is fact-specific and relies on a significant amount of evidence. While the implementation of the Swine Flu Act lowered the threshold requirements for some individuals, the United States informally applied it. Another approach to a compensation program would be to create a more formal time and symptom-based determination of causation.

One can imagine developing a schedule to facilitate the showing of causation. On one axis would be common symptoms from known adverse reactions. On the other axis would be the amount of time since vaccination that the symptoms occurred. Individuals who developed a listed symptom within the specified time would be able to recover damages on the presumption that the vaccine caused the injuries.

There is historical precedent for such a regime. Responding to a crisis in vaccine manufacturing and pricing, Congress passed the NCVIA in 1986. The centerpiece of the legislation is a no-fault compensation system based on a table of injuries. Individuals who suffer a "table injury" within the specified time can recover damages from the United States. This Part explores the NCVIA. The first section provides the historical context for the passage of the NCVIA. The second section describes its operation and the third section discusses the practical application of the NCVIA.

A. Background

The late 70's and early 80's were ripe for the development of a vaccine compensation system. The state vaccination programs were an enormous success with disease rates at all-time lows.¹⁹¹ Several estimates suggested that the success of the vaccine programs saved several billion dollars in health care costs. Additionally, the worldwide eradication of smallpox was recently completed. Despite the successes, these were difficult times for vaccine manufacturers. The evolution of the common law tort doctrines gave individuals an array of theories for pursuing damages. Additionally, parents became more aware of vaccine injuries and mobilized effort to address the issue. The increased awareness further fueled litigation.

By any measure, the effects devastated the vaccine industry. From 1983 to 1985, the price of the polio vaccine increased 140 percent and the price of DPT increased 230 percent.¹⁹² The extra money was not going in the manufacturers' pockets. For example, in 1983, the amount of liability claims against the DPT manufacturer Lederle exceeded their sales by 200 times.¹⁹³ Facing the uncertainty of the claims, many manufacturers were having difficulty buying liability insurance.¹⁹⁴ As a result many manufacturers stopped producing vaccines. By 1985, there was only one manufacturer of polio vaccine, one manufacturer of measles, mumps and rubella (MMR) vaccine, and two manufacturers of the DPT vaccine.¹⁹⁵ Many government officials viewed these developments as threatening the earlier successes.

Though plaintiffs' claims were increasingly successful, there was concern about the adequacy of the tort system as a compensation mechanism. While some plaintiffs won huge awards from the vaccine manufacturers, many deserving plaintiffs were shut out. Often the ability of plaintiffs to recover depended on the jurisdiction of the lawsuit. Some states determined that vaccines were unavoidably unsafe as a matter of

¹⁹¹ See S. Rep. No. 99-483, at 3 (1986).

¹⁹² See H.R. Rep. No. 99-801 (1986).

¹⁹³ See *National Childhood Vaccine Injury Compensation Act of 1985: Hearings Before the Committee on Labor and Human Resources*, 99th Cong. 229 (1985).

¹⁹⁴ See H.R. Rep. No. 99-908 (1986).

¹⁹⁵ *Id.* at 5.

law and did not permit design defect claims.¹⁹⁶ Additionally, many courts held that proximate cause could not be proven for duty to warn cases when the vaccine was state-mandated. Defendants based this clever defense on the reality that better disclosures would not change a decision to vaccinate when it was required to attend school. Even for plaintiffs who prevailed, the litigation process was often very timely and costly. As with many medical cases, there was significant complexity to the science and the facts surrounding an individual case.

During the early 1980's, the public became aware of the dangers of childhood vaccinations. A 1985 report by the American Medical Association estimated that sixty-three American children suffered from severe brain injury or death every year.¹⁹⁷ There were also highly publicized news programs including NBC's "Today" show and ABC's "Nightline."¹⁹⁸ As a result of the increased publicity, parents of injured children formed the "Dissatisfied Parents Together" group. This group soon allied itself with the American Academy of Pediatrics (the "AAP"). Since the late 70's, the AAP supported the idea of a no-fault compensation system for childhood vaccine injuries.¹⁹⁹ They crafted their position after several existing international programs. Though each group sought a no-fault system, they disagreed over its administration. The AAP wanted an expert group within the HHS to administer the program.²⁰⁰ On the other hand, the parents did not want authority in the hands of bureaucrats or medical experts.²⁰¹ Ultimately, the groups agreed to have a special master within the federal court system administer the program. In November 1983, Senator Paula Hawkins of Florida introduced the bill into Congress. The next June, Representative Henry Waxman of California introduced a companion measure in the House.

¹⁹⁶See, e.g., *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986) (holding that the Sabin polio vaccine was unavoidably unsafe as a matter of law).

¹⁹⁷American Medical Association Board of Trustees, *Report of Ad Hoc Commission on Vaccine Injury Compensation*, CONN. MED., March 1985, at 172.

¹⁹⁸See Francesca Lunzero, *Scared Shotless*, FORBES at 256 (1985).

¹⁹⁹Thomas Frederick Burke, *Litigation and Its Discontents: The Politics of Adversarial Legalism* 292 (1996) (unpublished Ph.D. dissertation, University of California Berkeley) (on file with author)

²⁰⁰Burke, *supra* note 199, at 296.

²⁰¹*Id.*

The bills met stiff resistance from various sources. The Reagan Administration was highly skeptical of a no-fault compensation system. Instead, they proposed to eliminate punitive damages and a cap on pain and suffering at \$100,000.²⁰² Obviously, vaccine manufacturers also resisted the compensation system. Instead, they supported a bill by Illinois Representative Edward Madigan that would create regional panels to arbitrate claims. Manufacturers would pay awards up to a \$1 million cap. Parents had the option of rejecting arbitration and bringing a traditional claim that would also be capped.²⁰³ Alternatively they could not bring an arbitration claim and bring a tort claim with uncapped liabilities.

Attempting to reach a compromise, Representative Waxman introduced a new bill that provided several safeguards for manufacturers if parents chose to bring a tort claim.²⁰⁴ Now facing strong opposition from DPT and other parent organizations, Waxman fiddled with the liability provisions. Afraid that President Reagan would veto the bill, Waxman included the bill as part of a health care omnibus provision. After Congress passed the bill, President Reagan signed it into law with much reluctance.

B. Statutory Operation

The NCVIA establishes a no-fault compensation for certain vaccines including the measles, mumps, rubella vaccine (the “MMR vaccine”), pertussis vaccines, diphtheria vaccines, tetanus vaccines, and polio vaccines.²⁰⁵ Special masters appointed by the United States Court of Federal Claims (the “Federal Claims court”) preside over the claims proceedings.²⁰⁶ The Federal Claims court has appellate jurisdiction over special masters decisions and reviews under an arbitrary and capricious standard.²⁰⁷ The NCVIA enables the Federal Claims

²⁰²*Id.* at 301.

²⁰³*Id.* at 303.

²⁰⁴The bill only permitted parents to file a civil claim after they brought a claim before the panel. The bill also eliminated the common theories of failure of the duty to warn and strict liability. Finally, claimants could not recover punitive damages. *Id.*

²⁰⁵42 U.S.C. §300aa-14(a).

²⁰⁶42 U.S.C. §300aa-12(c)(1).

²⁰⁷42 U.S.C. §300aa-12.

court to promulgate rules for the special master. The statute stresses that the rules should provide a less-adversarial, quicker, and more informal proceeding than normal claims in federal court.²⁰⁸

In order to bring a claim, the claimant must show that: (1) they received a vaccine set forth in the Vaccine Injury Table,²⁰⁹ (2) they received the vaccine in the United States,²¹⁰ (3) the vaccine caused the injury,²¹¹ (4) they suffered the injury for more than six months,²¹² and (5) they have not previously collected an award or settlement.²¹³ In proving causation there are three possibilities. If the claimant suffered an injury set forth in the Vaccine Injury Table (or “Table injury”) within the specified time then there is a presumption of causation.²¹⁴ On the other hand, if the claimant suffered a Table injury after the time specified then they must show traditional causation-in-fact.²¹⁵ Similarly, if the claimant suffered a non-Table injury then they must also show causation-in-fact.²¹⁶ The statute authorizes compensation when the claimant demonstrates these elements by a preponderance of the evidence and the government fail to show by a preponderance of the evidence that the injury was due to other factors.²¹⁷

The Vaccine Injury Compensation Trust Fund pays the compensation to the successful claimant.²¹⁸ It is funded by a seventy-five cent surcharge on every childhood vaccine.²¹⁹ The statute instructs the special master to determine compensation amounts based on medical expenses, lost earnings and pain and suffering.²²⁰ It does not allow the payment of punitive damages.²²¹ The statute gives the special master discretion to determine whether it is a lump sum payment or an annuity.²²²

²⁰⁸42 U.S.C. §300aa-12(d)(2).

²⁰⁹42 U.S.C. §300aa-11(c)(1)(A).

²¹⁰42 U.S.C. §300aa-11(c)(1)(B)(i)(I).

²¹¹42 U.S.C. §300aa-11(c)(1)(C).

²¹²42 U.S.C. §300aa-11(c)(1)(D).

²¹³42 U.S.C. §300aa-11(c)(1)(E).

²¹⁴42 U.S.C. §300aa-11(c)(1)(c)(i).

²¹⁵42 U.S.C. §300aa-11(c)(1)(c)(ii)(I).

²¹⁶42 U.S.C. §300aa-11(c)(1)(c)(ii)(II).

²¹⁷42 U.S.C. §300aa-13(a)(1).

²¹⁸42 U.S.C. §300aa-15(f)(4).

²¹⁹26 U.S.C. §4131(b)(1)(a).

²²⁰*See* 42 U.S.C. §300aa-15(a)(1)-(3).

²²¹42 U.S.C. §300aa-15(d)(1).

²²²*Id.* The statute requires that the special master base compensation on the present value of the payment. Courts have

The statute mandates that successful claimants receive compensation for past and future medical expenses. It requires that the expense (1) result from the vaccine injury (2) incurred by the person suffering the injury and (3) be incurred for diagnosis, treatment, or aftercare.²²³ In addition, the claimant must not receive reimbursement for expenses covered by other sources. There is significant litigation concerning whether claimed expenses are proper expenses for rehabilitation, vocational training and counseling.²²⁴ Finally, the statute authorizes the payment of \$250,000 for death.²²⁵

The statute permits the recovery of lost wages. For claimants sustaining injuries after their eighteenth birthday, the statute mandates determination of actual and anticipated lost earnings based on actuarial principles.²²⁶ For claimants sustaining injuries before their eighteenth birthday, lost wages is determined by subtracting taxes and average health insurance from the average wage of a private, non-farm sector wage earner.²²⁷ The special master does not take other factors such as education, professional level, or fringe benefits into account.²²⁸

The statute permits compensation for pain and suffering up to \$250,000.²²⁹ It mandates the special master to discount awards for future pain and suffering to present value.²³⁰ The courts are generally unreceptive to the arguments that severely debilitated children should not receive pain and suffering damages because they are physically unable to experience pain.²³¹

interpreted this statutory language to require the special master to not to adjust annuity payments for the time-value of money. As a result, payment of compensation through an annuity effectively reduces the amount received.

²²³42 U.S.C. §300aa-15(a)(1)(A).

²²⁴See, e.g., *Kleinhart v. Secretary of HHS*, 25 Cl. Ct. 173 (upholding compensation for family counseling to help deal with child's behavioral difficulties); *Stotts v. Secretary of HHS* 23 Cl Ct 352 (1991) (upholding an award of \$48,626.05 for architectural modifications to the family home to allow the child to remain).

²²⁵42 U.S.C. §300aa-15(a)(2).

²²⁶42 U.S.C. §300aa-15(a)(3)(A).

²²⁷42 U.S.C. §300aa-15(a)(3)(B).

²²⁸See *Edgar on behalf of Edgar v. HHS*, 26 Cl. Ct. 286 (Fed. Cl. 1992) (reasoning that to allow these considerations would eliminate the distinction between subsection (A) and subsection (B) of 42 U.S.C. §300aa-15(a)(3)).

²²⁹42 U.S.C. §300aa-15(a)(4).

²³⁰42 U.S.C. §300aa-15(f)(4). In calculating the amount of compensation, courts have held that pain and suffering damages should be determined up to the cap and then discounted to present value. See, e.g., *Youngblood v. Secretary of HHS*, 32 F.3d 552 (Fed Cir., 1994) (rejecting petitioner's argument that the statute capped the present value of compensation at \$250,000).

²³¹See, e.g., *Edgar on behalf of Edgar v. Secretary of HHS*, 26 Cl. Ct. 286 (Fed. Cl. 1992) (holding that parents of a child in a permanent vegetative coma could recover damages for pain and suffering).

The second part of the NCVIA allows plaintiffs to reject the results of the VICP and bring a state claim. Nevertheless, provisions of the NCVIA change the substantive contours of a state claim. First, the statute adopts Section 402A comment k of the Restatement (Second) of Torts. A vaccine manufacturer will not be held liable for unavoidable side effects if the vaccine was properly prepared and accompanied by warnings.²³² Second, the statute creates a presumption of adequate warnings if they comply with Food and Drug Administration standards.²³³ A plaintiff can overcome the presumption if they prove either (1) the manufacturer failed to exercise due care notwithstanding compliance²³⁴ or (2) the manufacturer engaged in fraudulent or intentional withholding of information.²³⁵ Finally, the statute states that manufacturers does not need to provide the warning to the individual. Some commentators call this provision a codification of the learned intermediary doctrine because the manufacturer discharges his duty when it supplies information to the doctor.

C. Results

The NCVIA accomplished several of its legislative purposes. One purpose was to stabilize the supply of vaccines so that more children receive vaccines. To this end, wholesale vaccine prices have decreased and childhood immunization rates have increased.²³⁶ Additionally, vaccine manufacturers are thriving with decreased pressures from litigation. No vaccine manufacturers have left the market and new innovations are starting to reach the market.²³⁷

Another goal of the NCVIA was to lower the burden on claimants to receive compensation for their injuries.

In achieving this purpose, the NCVIA has had mixed results. One positive result is that the average time

²³²42 U.S.C. §300aa-22(b)(1).

²³³42 U.S.C. §300aa-22(b)(2).

²³⁴42 U.S.C. §300aa-22(b)(2)(B).

²³⁵42 U.S.C. §300aa-22(b)(2)(A) and 42 U.S.C. §300aa-23(d)(2)(A).

²³⁶Derry Ridgway, *No-Fault Vaccine Insurance: Lessons from the National Vaccine Injury Compensation Program* 24 J. Health Pol. Pol'y L. 59, 62 (1999).

²³⁷*Id.* One recent cause for concern was the increased litigation over thiomerosal, a mercury-based additive to the DPT vaccine. As a last second rider to the HSA, Congress included thiomerosal in the NCVIA.

for claim determination has decreased to 20.3 months.²³⁸ However, the correctness of claim determinations is subject to dispute. One study reviewed every published eligibility decision since 1999 and found that 51.9% of claims led to awards.²³⁹ Rather than reviewing published decisions, other commentators cite the raw statistics as demonstrating that the VICP only compensates one third of the claims suggesting that the VICP did not provide enough compensation.²⁴⁰ Certainly, it is difficult to judge the effectiveness of the system without knowing the true number of injuries.

In published decisions, the majority of the denied claims were because of lack of causation.²⁴¹ Clearly, an advantage of the VICP is the availability of table causation. Only five percent of successful claims were non-table cases. The difficulty for claimants in these non-table cases is that they must establish causation-in-fact. This burden is difficult to meet because it is a fact-specific and scientific inquiry.

While the NCVIA has been a structural success, the biggest complaints have been directed at the administration. One problem is that awards vary greatly depending on the special master and the attorneys in the case. A recent study showed that success rates of claimants varied between 32.8 and 65.8 percent depending on the special master.²⁴² Additionally, success rates varied from 37.9 and 72 percent depending on the claimant's attorney.²⁴³ Both results are statistically significant and appear to contradict the NCVIA's goal of uniformity and certainty.

The biggest problem is the increasingly adversarial posture of the Department of Justice attorneys in defending against the claims. One purpose of the VICP was to provide faster and less adversarial adjudication of injury claims. In a recent report, the House Committee on Government Reform stated "the program under the direction of the HHS has approved changes that substantially restrict compensation coverage.

²³⁸Ridgway, *supra* note 236 at 64.

²³⁹*Id.*

²⁴⁰*See* Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 Food Drug L.J. 351 (2001).

²⁴¹Ridgway, *supra* note 236, at 65.

²⁴²*Id.* at 66.

²⁴³*Id.*

Furthermore, avoidable, protracted and adversarial litigation of claims has resulted thereby undermining the remedial nature of the program as intended by Congress.”²⁴⁴ As earlier stated, the average processing time is lower than litigation. Nevertheless, this number is misleading. Many claims, especially table claims, are handled quickly while non-table claims are not.²⁴⁵ Only fourteen percent of claims have been handled within one year and nineteen percent have been handled within one to two years.²⁴⁶

The cause of the delay is subject to dispute. The DOJ claims petitioners take a long time responding to requests for additional information. Data collected by the HHS shows that the special master requested additional medical information from half of the petitioners.²⁴⁷ Most petitioners took over a year to supply this information.²⁴⁸

On the other hand, many individuals claim that the adversarial nature of the DOJ prolongs the claim process. Before 1990, the special masters handled over ninety percent of the claims within two years. In 1990, however, the HHS and DOJ began to increasingly review the validity of the claims. The HHS began a program that used expert witnesses to scrutinize the causation of the injuries by trying to determine other causes including pre-existing seizure disorders.²⁴⁹ Additionally, the DOJ began to designate attorneys to specialize in handling the vaccine cases. After 1990, the number of claims handled within two years hovers around thirty percent.²⁵⁰

Other evidence also points to the increasingly adversarial role of the DOJ attorneys. In the case of *Marks v. Sec’y of HHS*, the special master said:

²⁴⁴H.R. Rpt. 106-977 2 Oct. 12, 2000 at 2.

²⁴⁵*See id.* at 12 (citing statements by the special master that “whether cases proceed under the Table or as causation-in-fact cases correlates directly to the amount of time, the number of issues presented, and the cost of processing cases.”)

²⁴⁶United States General Accounting Office, Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily at pg. 8. [hereinafter GAO Report]

²⁴⁷*Id.*

²⁴⁸*Id.* at 9.

²⁴⁹*Id.* at 10.

²⁵⁰*See* GAO Report, *supra* note 246, at 11.

[C]ounsel's abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial; and hindered greatly a fair, expeditious resolution to the case. In addition, simply lacks tact and compassion. Quite frankly, the special master is embarrassed that respondent's counsel and respondent's life care planner represented the United States government in this case.²⁵¹

In addition to an adversarial tone, critics point to several other aggressive tactics. First, the DOJ attorneys vigorously use tactics to impeach expert testimony. Second, they substitute one expert for another if they disagree with the opinion of the first expert. Finally, they repeat many arguments at the damages hearing that may have failed at the entitlement phase.²⁵²

In conclusion, the NCVIA has shortened the claim process and added simplicity to compensation claims. Nevertheless, there is substantial criticism that the practical implementation of the VICP does not fully achieve the Congressional purpose. Certainly any proposal for a smallpox vaccine compensation system based upon the NCVIA should address these concerns.

D. Conclusion

By providing table causation, the NCVIA has simplified and expedited the claims process for childhood vaccine injuries. Nevertheless, there is some dispute whether it has been successful in allowing recovery for every vaccine injury. The creation of an Office of Special Masters within the Court of Federal Claims established an infrastructure that allows claims to be heard by individuals with specialized expertise. While the mechanisms should expedite claim determinations, recent criticisms suggest that the claims process is taking too long. This complaint has been the focus of Congressional scrutiny and may result in amendments to the NCVIA.

²⁵²See *id.* at 12.

Part VI: 9/11 Victim's Compensation Fund

Both the Swine Flu Act and the NCVIA were compensation programs established over twenty years ago. The 9/11 VCF is a more recent compensation program that has been the subject of extensive criticism. Nevertheless, it is important to study in order to learn lessons for future programs. The first section reviews the history surrounding the passage of the 9/11 VCF. The second section discusses the operation of the compensation program. Finally, the last section reviews the implementation of the program.

A. Background

Following the tragic events of September 11, 2001, there was considerable concern about the financial stability of the airline industry. Already strapped for cash, the industry lost an estimated \$100 to \$275 million dollars each day that the federal government grounded flights.²⁵³ Once flights resumed, the number of passengers was much lower than normal. Additionally, United Airlines and American Airlines faced potential lawsuit from victims and their families.

Almost immediately after the events on September 11, the White House began circulating a two-pronged proposal to bailout the airline industry. First, it would make \$10 billion in loans and \$5 billion in cash available to the airline industry.²⁵⁴ Second, it would make the Southern District of New York the exclusive forum for a Federal cause of action against the air carrier. Additionally, it would limit the liability to the extent of the insurance coverage maintained by the air carrier. Only ten days after September 11, Congress passed these provisions in the Air Transportation Safety and System Stabilization Act (the "ATSSA").²⁵⁵

ATSSA, however, contained a third provision written hours before its passage as a result of extensive partisan negotiation.²⁵⁶ This provision established a no-fault compensation system for victims of the events of

²⁵³Laurence Zuckerman, *After the Attacks: Financial Struggle; Airlines, in Search of Relief, Warn of Bankruptcy*, N.Y. TIMES, Sept. 15, 2001, at A1.

²⁵⁴*Id.*

²⁵⁵*See* 49 U.S.C. §40101.

²⁵⁶Diana B. Henriques and David Barstow, *A Nation Challenged: Victim's Compensation; Fund for Victims' Families Already*

September 11. Its history began two days before the passage of ATSSA, when lobbyists for the American Trial Lawyers Association floated the idea of a compensation fund for victims. Senate Majority Leader Tom Daschle and House Minority Leader Richard Gephardt soon made it clear to other members of Congress that they would not support airline relief without the establishment of a compensation fund. The White House had already proposed a plan to consolidate all litigation in the Southern District of New York. In this plan, plaintiffs would have to prove negligence and the federal government would pay for any damages exceeding the insurance coverage. Democrats were now pushing their plan in its place.

Many Republicans resisted the Democrats' plan because it did not cap liability.²⁵⁷ Additionally, Senator Don Nickles of Oklahoma expressed concern about the fairness to victims of other terrorist attacks such as the Oklahoma City bombing.²⁵⁸ In a twenty-four flurry before the passage of ATSSA, Congress finalized the details of the 9/11 VCF. In return for no limitations on compensation, Democrats agreed to two conditions. First, any compensation award would be offset by money received from other sources such as insurance. Second, the Attorney General would appoint the special master.²⁵⁹

On November 26, 2001, Attorney General John Ashcroft chose Kenneth Feinberg as special master. During the initial stages of the selection process, former Senators John Danforth of Missouri and George Mitchell of Maine were mentioned as possible candidates.²⁶⁰ Mr. Feinberg, however, expressed interest to Senator Charles Hagel of Nebraska and also received support from New York Senator Charles Schumer. An unusual nominee for a Republican administration, Mr. Feinberg was a practicing lawyer and former chief of staff for Massachusetts Senator Edward Kennedy. He distinguished himself as a negotiator in some of the most famous mass-tort cases: Agent Orange, DES, Dalkon Shield, and breast implants. Indeed some of the qual-

Proves Sore Point, N.Y. TIMES, Oct. 1, 2001, at A1.

²⁵⁷*Id.* Responding to concerns about the cost of the fund, Senator Daschle responded "Do you want to put a value on human life right now? I don't." *Id.*

²⁵⁸*Id.*

²⁵⁹*Id.* In their initial proposal, Democrats wanted a senior judge approved by the Senate to act as special master of the fund.

²⁶⁰Elizabeth Kolbert, *The Calculator: How Kenneth Feinberg Determines the Value of Three Thousand Lives*, THE NEW YORKER, Nov. 25, 2002, 42.

ities that make him excel in this field also lead him to clash with claimants. Nevertheless, he was given the broad discretion to operate the fund.

B. Operation

The stated pupose of the 9/11 VCF is to “provide compensation to any individual (or relatives of a deceased individual) who was physically injured or killed as a result of the terrorist-related aircraft crashes of September 11, 2001.”²⁶¹ The 9/11 VCF gives the attorney general the power to appoint a special master who administers the compensation program and promulgates all procedural and substantive rules.²⁶² It allows individuals injured in the crashes or the personal representatives of individuals killed to file a claim with the special master.²⁶³

For an individual to be eligible, they must satisfy the presence and physical harm requirements. To satisfy the presence requirement, the person must have been at the World Trade Center, the Pentagon, or the Shanksville, Pennsylvania crash site at the time of the crash or in the immediate aftermath.²⁶⁴ The final regulations define the “immediate aftermath” as ninety-six hours for rescue workers and twelve hours for everyone else.²⁶⁵

The final regulations also set a temporal limit on the physical harm requirement. A medical professional must have treated the injury within twenty-four hours of the injury or the individual’s rescue.²⁶⁶ For those who did not realize the extent of their injuries or could not obtain medical care, the time limit is seventy-two hours.²⁶⁷ For rescue workers who could not obtain medical care within seventy-two hours, the regulation gives the special master discretion to choose the appropriate limit.²⁶⁸

The determination of damages is perhaps the most contentious part of the 9/11 VCF. Submission of a claim

²⁶¹Air Transportation Safety and System Stabilization Act, Pub. L. 107-42, 115 Stat. 230 §403 [hereinafter ATSSSA].

²⁶²*Id.* at §404(a)(1) - (2).

²⁶³*Id.* at §405(c)(2)(A)-(C)

²⁶⁴*Id.* at §405(c)(2)(A)(i)

²⁶⁵28 C.F.R. 104.2(b)

²⁶⁶28 C.F.R. 104.2(c)

²⁶⁷*Id.*

²⁶⁸*Id.*

to the special master waives any right to file a claim in state or federal court for the damages suffered.²⁶⁹ To help individuals make an informed decision, the special master published a table providing the estimated awards available to claimants. Individuals deciding to file a claim must provide information about the physical harm,²⁷⁰ economic and non-economic losses,²⁷¹ and information on any collateral offset of losses.²⁷² In determining the presumed income, the special master uses the human capital approach to valuation. The economic theory behind this method is an attempt to estimate the present value of all the money an individual would receive over their lifetime. The calculation involves estimating an individuals' future income and subtracting their future consumption. In implementing this approach, the special master starts with the age of the claimant and their after-tax compensable income plus benefits.²⁷³ The special master then projects this income stream over the work-life expectancy taking into account inflationary changes and unemployment risks.²⁷⁴ From this number, the special master subtracts the decedants' annual consumption. The special master then calculates the present value of this future income stream using a discount rate based on current yields of mid- to long-term Treasury securities.

The special master calculated these values for a variety of ages and wages. For example, a twenty-five year-old married individual with no children who earned \$100,000 per year has a presumed economic and non-economic loss of \$4,425,645.²⁷⁵ On the other hand, a similarly situated fifty year-old earning \$50,000

²⁶⁹ATSSSA, *supra* note 261, at §405(c)(3)(B)(i). Additionally, an individual with pending litigation must withdraw her claim within ninety days of the establishment of the regulations.

²⁷⁰*Id.* at §405(a)(2)(B)(i).

²⁷¹*Id.* at §405(a)(2)(B)(ii). The statute defines economic loss as “any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.” *Id.* at §402(7). It defines non-economic loss as “losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.” *Id.* at §402(9) In the final regulations, the presumed non-economic loss is \$250,000 plus \$100,000 for a spouse and each dependant. 28 C.F.R. 104.44

²⁷²ATSSSA, *supra* note 261, at §405(a)(2)(B)(iii).

²⁷³United States Department of Justice, *Explanation of Process for Computing Presumed Economic Loss*

²⁷⁴*Id.* The special master used the expected work-life of “All-Active Males” regardless of gender. On average, men have a longer expected work-life than women of the same age.

²⁷⁵United States Department of Justice, *Presumed Economic and Non-Economic Loss for a Married Decedent with No Children Before Any Collateral Offset* (available at http://www.usdoj.gov/victimcompensation/vc_matrices.pdf).

has presumed losses of \$802,228.²⁷⁶

Additionally, the special master must offset the compensation award by any payments “related to the terrorist-related aircraft crashes.”²⁷⁷ This provision means that the special master subtracts life insurance proceeds from the calculation. Punitive damages are unavailable.²⁷⁸ The special master must make his determination in 120 days and the payment twenty days after the determination.²⁷⁹ The process affords the claimants some due process protections. During the process, claimants can be represented by an attorney and present evidence.²⁸⁰ Claimants can appeal awards but the special masters also hear the appeals.²⁸¹

C.

Results

The 9/11 VCF has been underutilized and subject of much criticism. As of February 25, individuals have submitted 1050 claims and the special master has provided award notifications to 176 individuals.²⁸² Fifteen percent of individuals responding to award notifications have filed an appeal.²⁸³ Compared with claims filed under the NCVIA or tort claims, the notification time is quick. Nevertheless, only one third of potential claims have filed for awards.²⁸⁴ Many potential claimants are reluctant to file because they think the compensation system is unfair.²⁸⁵ They would prefer to take their chances in court rather than accept a low claim award.

²⁷⁶ *Id.*

²⁷⁷ ATSSSA, *supra* note 261, at §405(b)(6) and §402(6).

²⁷⁸ *Id.* at §405(b)(5).

²⁷⁹ *Id.* at §405(b)(3) and §406(a).

²⁸⁰ *Id.* at §405(b)(4)(A) - (B).

²⁸¹ On February 18, fifteen percent of claims had been appealed. The special master expects all appeals to be heard by the end of 2004. *See* David W. Chen, *A Slow Deliberate Process of Judging 9/11 Victim Awards*, N.Y. TIMES, Feb. 18, 2003, at B1.

²⁸² United States Department of Justice, *September 11th Victim Compensation Fund of 2001: Award Notification and Distribution*, available at <http://www.usdoj.gov/victimcompensation/payments.html> (last visited Feb. 25, 2003).

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *See, e.g.*, David Chen, *supra* note 281, at B1.

Since the inception of the fund, there have been numerous criticisms about the method of calculating compensation. At the start of the fund, the collateral offset provision was a large source of contention. The final regulations excluded charitable donations from the definition of a collateral offset.²⁸⁶ Some contend that Congress intended these payments to be offset. Nevertheless, the special master excluded these payments under pressure from charitable organization who threatened to withhold their charity payments.²⁸⁷ An additional source of contention is that collateral offsets penalize those individuals who bought life insurance and benefits risk takers who did not purchase the appropriate level of insurance. In particular, the collateral offsets greatly reduce the returns of high wage earners who purchased policies commensurate with their projected income stream but received reduced payments from the fund.

Once the special master issued the compensation tables, there were additional complaints of unfairness from both high wage earners and low wage earners. The compensation tables highlight the equity issues of the compensation program. Families of lower wage earners argue it is unfair to give them five or ten times less than the amount other individuals are receiving. For some claimants, it is a money issue. They need the compensation to support the family, pay tuition, or retire on time. For other claimants, it is an affirmational issue. They argue that the government is devaluing the life of their loved one by offering a lower amount.

In meeting with the families, the special master often responds to this criticism by noting that Congress required economic harm to be considered.²⁸⁸ This statement is partially true. While the statute does state that economic harm should be taken into account, it also states that the special master should consider individual circumstances. In fact, a reporter for the New Yorker “heard him promise to give a widow an

²⁸⁶28 C.F.R. 104.47(b)(1). The final regulation exclude several payments from the collateral offset: (1) charitable gifts such as housing, food, or clothing, (2) charitable donations distributed by privately funded charitable entities, and (3) tax benefits from the Federal government. 28 C.F.R. 104.47(b)(1)-(3).

²⁸⁷In an interview with the New York Times, Mr. Feinberg stated that the charities threatened to “hold up distributing the charitable money until I cut each family’s check...so they wouldn’t be subsidizing the taxpayer...I blinked. I’m not going to hold up \$2.5 billion worth of charity.”

²⁸⁸Responding to this question from a mother on Staten Island, Special Master Feinberg said “What you’re really asking is: All lives are equal, why isn’t everybody getting the same amount of money?...A very fair question, ladies and gentlemen. The answer is: Congress told me that is not the way to compute these awards. Congress said you must take into account the economic loss suffered by the victim’s death.” Kolbert, *supra* note 260, at 44.

additional half million dollars for no other reason than that she had come in with her two small children and asked for it.”²⁸⁹

Claimants at the upper end of the claim chart also are complaining about their distributions. The construction of the chart underscores some of their complaints. First, the special master only published information for individuals earning less than \$225,000. Second, the special master filled in the cells for young high-wage earners with X’s. These clues underlie an approach that takes to heart the advice of Senators Kennedy and Hagel to not “let twenty percent of the people get eighty percent of the money.”²⁹⁰ Though the actual economic loss might be much greater, the special master indicated that he will rarely give out more than six million dollars.

Recently, seven relatives of victims who worked for Cantor Fitzgerald filed a lawsuit against the special master.²⁹¹ The lawsuit has four major contentions that repeat many of the concerns Cantor Fitzgerald expressed to the Department of Justice in a report compiled by the law firm Skadden, Arps and the consulting group Chicago Consulting.²⁹² First, the lawsuit contends that the special master incorrectly used after-tax income to calculate the lost earnings.²⁹³ In calculating lost earnings, the special master adhered to the human capital method of using after-tax earnings. The theoretical justification is that the wage earner would only have after-tax income to use for consumption. The plaintiffs claim that the special master should have followed New York law that requires the use of pre-tax income in determining wrongful death awards. Depending on the age and the income level of the deceased, this change could increase some awards by more than one million dollars.

The second claim is that the special master should have applied a uniform rate of consumption between

²⁸⁹*Id.*

²⁹⁰*Id.* at 42.

²⁹¹David W. Chen, *7 Families Sue Administrator of 9/11 Fund*, N.Y. TIMES, Jan. 27, 2003, at B1.

²⁹²See Submission of Cantor Fitzgerald L.P., Espeed, Inc. and Tradespark, L.P. to the Special Master of the September 11th Victim Compensation Fund of 2001 to the Department of Justice available at [hereinafter Cantor Fitzgerald Report]

²⁹³See David W. Chen, *supra* note 232, at B1

married and single individuals.²⁹⁴ According to the human capital method, income consumed should be subtracted from income earned. Individuals who are married consume less than single individuals because of economies of scale and the availability of the spouse's supplemental income. For example, they may share utility payments, car payments and food expenses. Additionally, payments come from both spouses' paychecks. On the other hand, New York law treats married couples and single individuals identically.²⁹⁵ The different treatment could have a significant effect on awards. For example, a single individual who earns \$70,000 will spend on average 60.8 percent for personal expenses. Married individuals, however, only spend 17.8 percent of their income.²⁹⁶

The third claim has several parts. First, it argues that the special master should have used income data from 2001 to calculate the average income.²⁹⁷ Second, the claim argues that the special master should have used the New York salary growth rate rather than the national growth rate.²⁹⁸ Finally, it argues that the calculation should have considered other forms of compensation including bonuses and stock options.²⁹⁹

Many of the criticisms underscore the larger issue of the amount of discretion given to the special master. He was given incredibly broad powers ranging from promulgating the regulations to reviewing the decisions. Additionally, there is little transparency throughout the process. Nevertheless, some claimants are pleased with the process and its relatively expeditious determinations.

D.

Conclusion

²⁹⁴ *Id.*

²⁹⁵ See Cantor Fitzgerald Report, *supra* note 292.

²⁹⁶ See David Chen, *supra* note 291, at B1.

²⁹⁷ *Id.*

²⁹⁸ *Id.*

²⁹⁹ *Id.*

Congress quickly constructed the 9/11 VCF to provide compensation for those killed and injured on September 11th. Since its inception, the 9/11 VCF has been the subject of extensive criticisms. Nevertheless, it is important to study for several reasons. First, many critics question the method of calculating compensation. Second, it is an interesting study for the appropriate discretion to give to the special master.

Part VII: Discussion

Clearly the current patchwork approach to compensation created by HSA Section 304 and workers' compensation does not provide comprehensive coverage for smallpox vaccine injuries. As a result, first responders have been relatively unresponsive to the vaccination effort. The last three sections explored other approaches to compensation programs and tried to draw lessons from their successes and failures. This part relies on the previous parts to construct a smallpox vaccine compensation program that will provide the proper incentive for first responders to receive the vaccine. The first section outlines a proposed smallpox vaccine compensation program. Though it outlines the potential provisions piecemeal, the proposed program draws heavily from the NCVIA. The second section reviews a recent House bill to establish a compensation program. Finally, the third section outlines a newly introduced proposal by the HHS.

A.

A Proposal for a Smallpox Vaccine Compensation Program

This section outlines a proposal to compensate certain individuals for smallpox vaccine injuries. Each subsection addresses the policy justifications for a particular provision and draws from the discussion in previous parts. When viewed as a whole, this program would be closely related to the NCVIA.

1. Complete Liability Waiver with Governmental Right of Contribution

In constructing a compensation system, it is important to determine who should bear the cost in the first instance. Under a traditional liability regime the vaccine manufacturer compensates plaintiffs for their injuries. As the examples in this article illustrate, many compensation systems shift the burden to the government. As with the childhood vaccines, this section recommends an exemption from liability for smallpox vaccine manufacturers in order to insure a stable and cheap supply of vaccines.

It is clear from the Swine Flu Act and the NCVIA that vaccine manufacturers will not produce the smallpox vaccine without liability protections. In both cases, the uncertainty of litigation made it difficult to obtain liability insurance.³⁰⁰ Without cost effective liability insurance, vaccine manufacturers must either self-insure or leave the market. During the vaccine crisis of the 1980's, the market for some vaccines shrunk to one manufacturer.³⁰¹ Many vaccine manufacturers were pharmaceutical companies with diversified businesses. As such, they were able to withstand any short-term detriment as they reallocated capital to other projects. Those companies remaining in the market priced their vaccines prohibitively high. As a result the incidence of illness increased at the end of the 1980's vaccine crisis. With some experts calling the smallpox vaccine the most dangerous vaccine available, escalating prices and market exodus would occur if manufacturers were exposed to liability.

Additionally, traditional policy considerations do not favor imposing liability on the vaccine manufacturer. First, manufacturers are not the cheapest cost avoiders because they produce unavoidably unsafe products. Regardless of the manufacturer's precautionary steps in producing the vaccine, some individuals will suffer adverse reactions. Second, it is not sound policy to have vaccine manufacturers spread the costs. In the initial stages, distribution of the smallpox vaccine will be limited and liability exposure will be high. Spreading the cost through the vaccine price would significantly raise the price. This situation is much different than the facts of *Escola* where imposing liability without fault had a vanishingly small effect on the price of

³⁰⁰ See discussion *supra* Part V, Section A.

³⁰¹ *Id.*

Coke. Indeed the price of the DPT vaccine more than doubled in two years during the vaccine crisis of the mid-80's.³⁰² Additionally, it would spread the costs too narrowly. Rather than the general public, the “consumers” of the vaccine are first responders. These individuals are principally state employees and health care professionals. In a time of state budget crises and escalating health care costs, these entities are in no position to act as deep pockets.

However, a program should not completely exempt manufacturers from paying in all circumstances. Certainly the biggest concern with a total exemption is it creates a disincentive to take optimum precautions in manufacturing vaccines. Obviously a major purpose of the tort system is to provide incentives to take cost-justified measures. If there were no recovery from manufacturers then there would need to be other sources of quality control. A traditional source of quality standards is the market. If the market demands quality goods, then manufacturers must compete for customers on the basis of quality. However, several characteristics cast doubt on the efficiency of the vaccine market. First, it is probably not informationally efficient. Assuming that there was a selection of vaccines with varying quality, it is not clear that the consumer could find information, analyze it, and make the proper choice. Second, it is not a competitive market. Vaccine manufacturers have an oligopoly meaning there will be little market-based quality competition.

In addition to potential market controls, there are regulatory controls. The major justification for regulatory control is the failure of the market to regulate quality. The FDA is an external source of quality control for biologics. If we believe that the FDA effectively regulates manufacturers, then a liability provision would be redundant. Under this assumption, a compensation system could exempt manufacturers without effecting the quality of the vaccine. As a practical matter this approach is not prudent. While the FDA does an

³⁰²*Id.*

excellent job of quality oversight, the threat of litigation is always in the background.

None of the three historical approaches provided a complete waiver to manufacturers. While The Swine Flu Act did not allow the injured party to sue the vaccine manufacturer directly, it did allow the government a right of contribution for negligent or reckless conduct. On the other hand, the VICP allows claimants to file suit in federal court after they reject the findings of the special master. Finally, like the Swine Flu Act, the 9/11 VCF also allowed a right of contribution by the United States against a negligent manufacturer.

Additionally, some argue that public confidence in the Vaccination Plan may decrease if the manufacturers were exempt from liability. This argument is not compelling. At present, the consumers of the vaccine are limited to the first responders covered by Secretary Thompson's declaration. The immediate concern is the incentives of this narrow group to receive the vaccine. Press accounts characterize their main concern as uncertainty about compensation rather than poor manufacturing quality control.

An alternative to an absolute exemption would be an exemption for all non-negligent actions by the manufacturer. This approach would retain the incentive to act non-negligently. There are several possibilities. One possibility would be to allow private rights of action against manufacturers. While this approach would result in enforcement, it may also result in excessive litigation. Though they were often unsuccessful, plaintiffs brought many cases against the United States under the Swine Flu Act on negligence theories. Another possibility would be to allow the United States to bring claims against a manufacturer for negligence. Both the Swine Flu Act and the 9/11 VCF adopt such an approach. Such a provision provides the appropriate incentives while curbing the possibilities of nuisance litigation.

In conclusion, any compensation program must exempt manufacturers from liability. Significant exposure

to liability could destroy the infrastructure for vaccine innovation. Nevertheless, some mechanism must be available to ensure quality. This section argues for a right of contribution by the U.S. against vaccine manufacturers.

2. Compensation System for First Responders

Having determined the extent of manufacturer liability, the next step is to determine eligibility. This section argues for the availability of compensation for first responders and those individuals secondarily-infected by first responders.

The argument for compensating first responders is stronger than the traditional justification for vaccine injury compensation. For traditional vaccines, there are two levels of health policy. At the individual level, it is clear that some vaccines provide a net benefit to the vaccinee. For these vaccines, public health officials have determined that the probability and magnitude of harm from the disease is greater than the probability and magnitude of harm from potential side effects of the vaccine. As a result, a rational individual would choose to receive the vaccine. Clearly, some individuals will suffer side effects. From an *ex post* perspective, they would not have decided to receive the vaccine. Nevertheless, this fact should not change their decision *ex ante*.

Presumably, every individual faces the same probability of suffering an adverse side effect. In a world of costless contracting, individuals would negotiate with each other before vaccination to pool money to pay for an injury. This arrangement would serve as a type of insurance. Obviously, transaction costs makes this a practical impossibility. However, a statutory system of compensation serves the same purpose.³⁰³

The argument becomes stronger with the addition of the group level justification that vaccination benefits the public as well as the vaccinee. When there is no immunity to disease, it passes from person to person with

³⁰³For an excellent discussion of the economics of vaccine policy, see Michael I Krauss, *Vaccines and Products Liability* in PRODUCTS LIABILITY (Matthew Bender) ¶51.04.

each person serving as a reservoir for the pathogen. When individuals have immunity, they are no longer reservoirs of the pathogen and will not spread the disease. As a result, only unvaccinated individuals can spread the disease to other unvaccinated individuals. As the number of unvaccinated individuals decreases, the likelihood that two unvaccinated individuals will come in contact to transfer the disease also decreases. This effect is known as “herd immunity.”³⁰⁴

Herd immunity, however, actually creates the perverse incentive for individuals to free-ride immunity from vaccinated individuals. People will no longer risk a vaccine injury to receive immunity because herd immunity protects them. Free-riding becomes a problem if enough people forgo vaccinations because there will no longer be herd immunity. Compensation for vaccine injuries counteracts this incentive by reducing the downside risk of vaccination.

The Vaccination Program involves an entirely different calculus because the public is the chief beneficiary. According to the CDC Draft Proposal, the risk of a smallpox outbreak is not high enough to justify the risk of vaccinating the general public.³⁰⁵ In this case, the probability and magnitude of an injury from smallpox exposure is less than the probability and magnitude of a vaccine injury. Rational individuals would not choose to be vaccinated.

However, it is not an individual calculation for first responders. The calculation must include the benefit to the public rather than just to the individual. The public benefit of vaccinating first responders is the ability to perform their duties during a smallpox attack without the fear of infection. In the CDC’s view, the probability and magnitude of injury to the public is greater than the probability and magnitude of injury to the first responder.³⁰⁶ Therefore, they recommended that first responders receive the vaccine. In a world of costless contracting, the general public would aggregate and pay the first responders to assume the risk of vaccination in order to provide protection. A compensation program merely provides the same result. The

³⁰⁴ *Id.*

³⁰⁵ ACIP Proposal, *supra* note 9, at 1.

³⁰⁶ *Id.*

public is paying for vaccine injuries because it would benefit if there were a smallpox attack.

Clearly this argument has a moral component and an efficiency component. The moral claim is that society should repay individuals who sacrifice themselves for the benefit of society. This justification applies to both first responders and to individuals secondarily infected by first responders. Certainly, this justification has strong moral appeal but it is not uniformly applied in our society. Some of the most vocal opponents of the 9/11 VCF were relatives of people killed attempting everyday acts of “heroism.” For example, the special master received a letter from a widow of a husband who died trying to save a drowning child in a swollen river.³⁰⁷ Why, she asked, does society owe a debt of gratitude to one set of heroes and not another? Clearly, she is correct. If there were a moral justification for compensating one set of individuals then certainly that same justification would apply to the other.³⁰⁸ But this does not mean that no one should receive compensation.

The other component of the argument is efficiency. The vaccine will injure some first responders and they will sue. A compensation program would be justified if the sunk costs of vaccination and compensation were less than the expected value of expenses paid in the future without a vaccination program. These costs include medical expenses for injuries that would not have occurred if first responders were vaccinated and any litigation costs associated with vaccine lawsuits. The “expected value” of these costs is the probability of paying this sum multiplied by the sum. If the expected value were greater than the current costs of compensation then a compensation program would be justified on efficiency grounds. Certainly, this calculation is difficult because it requires assigning a probability to the risk of smallpox attack.

While one can make this efficiency argument, the strongest argument is pragmatism. As described in the

³⁰⁷Kolbert, *supra* note 260, at 45.

³⁰⁸Pragmatic reasons seem to underlie the asymmetric compensation of individuals. Unfortunately, September 11 brought economies of scale to tragedy and heroism. Deserving individuals were so numerous that it provided the opportunity for cost-effective compensation. However, the driving factor was not a desire to repay our moral debt. Rather, it was an efficiency decision to avoid the litigation costs and the possibility of bankrupt airlines. Clearly, a similar justification may support compensation for first responders.

introduction, the Vaccination Plan is currently stalled because first responders are demanding adequate protections. If the policy goal is complete participation in the Vaccination Plan, then compensation must be made available to first responders. As long as the Vaccination Plan is voluntary, then the first responders have leverage to demand compensation. Similarly, if first responders will not receive the vaccinations unless society compensates secondarily-infected individuals, then pragmatic concerns also justify compensation of secondarily-infected individuals.

In conclusion, there are several justifications for compensating first responders and secondarily-infected individuals. First, there is the moral argument that society should repay people who sacrifice themselves for its benefit. Second, there may be an efficiency argument that society will probably enjoy a benefit worth more than the cost of compensation. Finally, there is the pragmatic consideration that voluntary vaccinations will not be successful without these provisions. As a result, this Article recommends compensating first responders and secondarily-infected individuals.

3. No Compensation System for Non-First Responders

There is no justification for compensating non-first responders until President Bush widens the Vaccination Plan. First, the individual-level justification for compensation does not apply. There is no public bargain because a majority of the public is not receiving the vaccine. Until smallpox vaccinations are nationally mandated, only a certain number of individuals would receive the vaccine. Costless contracting would only occur between those who received the vaccine so the group would be much smaller than the general public. Second, there is no herd immunity because a majority of the public will be unvaccinated. In the absence of a desire for herd immunity, there is less reason to incent vaccination. Finally, these individuals would receive the vaccine solely for their own benefit rather than to allow them to benefit society. As a result, none of the justifications apply to non-first responders. If the President were to extend the Vaccination Plan to the general public then there would be a compelling case for a complementary compensation scheme.

4. Tort Approach Rather Than Workers' Compensation

Having established the need to compensate first responders for vaccine injuries, it is now necessary to discuss the structure of the compensation system. Currently, there is a two-tier system consisting of workers' compensation and tort recovery. Either compensatory mechanism could be used as a doctrinal anchor for a compensation system. Indeed their operation would be similar in many circumstances. Nevertheless, a tort-based system is better than a workers' compensation-based system because it can address situations that would doctrinally stress a workers' compensation-based system.

As discussed in Part III, workers' compensation is available for federal workers under FECA and to non-federal employees depending on substantive state regulations. Certainly, one approach to compensation would be to create a uniform system of workers' compensation. This approach could operate through one system at the federal level or through mandatory substantive minimums at the state level. For most cases, this approach would be a straight-forward inquiry into whether the injury arose from employment. Since "arising from employment" would essentially mean "arising from vaccination," the inquiry would be similar to tort-based causation. Additionally, a workers' compensation-based system could use causation tables to facilitate recovery.

Nevertheless, the workers' compensation model is less effective for injuries arising from secondary transmissions. Many public health officials cite the real possibility that first responders will unintentionally transmit the vaccinia virus to other individuals. Of particular concern is the possibility that physicians will transmit the virus to at-risk individuals such as the immuno-compromised.³⁰⁹ Another concern is the transmission to family members. In either case, compensation for the secondarily-infected clearly falls outside the traditional model of workers' compensation. At the federal level, FECA handles this problem by deeming some secondarily infected individuals to be within reach of the provisions. Certainly, this statutory fiction is one

³⁰⁹ See discussion *supra* Part II Section E.

way within workers' compensation to permit recovery for the secondarily infected. Nevertheless, in creating a system from scratch, the more doctrinally pure approach would be tort-based.

A tort-based approach would import the traditional inquiry into the compensation system— duty, breach, causation, and injury. Adopting a strict liability like recovery would eliminate the need to show a duty or a breach of that duty. Instead, a person could receive compensation if they showed that they were injured and that the vaccine caused the injury. By limiting the showing to causation and injury, this doctrinal framework more easily handles the problem of compensating the secondarily infected than a workers' compensation approach.

5. Table Causation

For drug and vaccine litigation, causation is often the most difficult obstacle to recovery. During the Swine Flu litigation, the government informally reduced this burden by settling the easy cases. This approach provided quick compensation to individuals clearly suffering from GBS. The NCVIA followed suit by establishing a formal system of presumptive causation for Table Injuries. Though it is the subject of some criticisms, the NCVIA has been a relative success. For injuries falling under the Vaccine Table, this method has greatly expedited claim determinations. Certainly this approach could be adopted for smallpox vaccine injuries. For injuries listed on the table, the claims process would be greatly simplified. As a result, this Article recommends enacting a vaccine injury table for the smallpox vaccine.

While a vaccine injury table reduces the burdens during claim determination, it would require significant time and effort to construct. The difficulty of implementing a smallpox vaccine injury table would vary by injury. For many cases, the link between an injury and the vaccine would be clear. Side effects such as progressive vaccinia, generalized vaccinia and eczema vaccinatum will have characteristic physical symptoms.³¹⁰ For these injuries, proof of causation should not be difficult and the claim process should be swift.

³¹⁰See discussion *supra* Part 2 Section D.

Additionally, it should be relatively simple to construct an injury table for these side effects.

Unfortunately, the most difficult cases from a causation standpoint will also be the most difficult medically to diagnose. Both postvaccinial encephalopathy and encephalitis are rare but life-threatening side effects of the smallpox vaccine. Their clinical symptoms are largely neurological and may be unaccompanied by any dermatological abnormalities.³¹¹ Clearly it would be hard to establish causation-in-fact for these side effects. Undoubtedly a vaccine table would facilitate recovery but it could be difficult to design. These side effects do not present unique symptoms that would distinguish it from other causes. Rather, experts would need to collect data on incidence rates and time periods that would estimate causation to an acceptable statistical level. A more liberal temporal component would permit some recovery unrelated to the smallpox vaccine. A more stringent approach would fail to compensate all vaccine injuries. Regulators would have to try to strike the proper balance between these positions.

The design of the vaccine table will be even more complicated for secondary transmissions. The current VICP Injury Table creates a matrix of symptoms and time limits. A vaccine table including secondary smallpox transmissions may be unable to contain the temporal component because claimants would not know when they came in contact with a vaccinated individual. For the “dermatological” side effects, the lack of temporal information may be inconsequential because the physical manifestations are clear. A clinically characteristic lesion would indicate vaccinia contact without knowing when the contact occurred. For neurological side effects, the task would be much more difficult.

Though there will be some difficulties designing the vaccine table, it would create benefits by simplifying the claims process. If one goal of the compensation program is to reduce administrative burdens, then it should include a simplified method for proving causation. Though it would require some initial work, a vaccine injury table is the best approach to facilitating recovery.

³¹¹*Id.*

6. Table Compensation

As shown by the underwhelming response to the 9/11 VCF, the success of a compensation system depends heavily on the method of determining compensation. If the compensation is too low or if it is perceived as unfair, then people will not participate. This section analyzes the different approaches and components to compensation. It recommends reimbursement of medical expenses, uniform damages for pain and suffering, and damages for economic losses determined by the human capital method.

In crafting the compensation arrangement for injuries there are several policy considerations. First, the system should be horizontally equitable meaning that the program should compensate similarly situated individuals the same amount. One criticism of the 9/11 VCF is that it creates some horizontal inequities. The discretion conferred to the special master by Congress allows him to augment the table compensation. Indeed there are instances where he increased a compensation award beyond the table amount.³¹² Second, some people argue that the system should be vertically equitable meaning that it treats different people differently. There is less support for vertical equity than horizontal equity. Finally, and most importantly, the compensation system should provide the proper incentives to receive the vaccine. If the goal of the compensation system is to induce first responders to be vaccinated, then it should be structured to accomplish this goal.

Several policy considerations are in tension with these concepts. First, it is unlikely that any system would have open-ended compensation. A criticism of the 9/11 VCF from both sides of the aisle is its failure to cap liabilities. Despite an explicit statutory mandate, the special master has exercised his discretion to hold down the cost of the program. The legislative history of the 9/11 VCF shows that the hurried circumstances

³¹²See discussion *supra* Part VI Section C.

resulted in an uncapped program. Any legislation under less time pressure would receive significantly more scrutiny. With budgetary constraints, it may be impossible to accomplish every policy goal. A second policy consideration is administrability. Any compensation system that attempts to minimize vertical and horizontal inequities may be administratively burdensome.

With these policy considerations as background, there are three possible approaches to compensation. The first approach would pay a uniform amount to a victim. For example, the VICP pays \$250,000 for a death. Similarly, the 9/11 VCF creates a presumption of \$250,000 for non-economic damages. The advantages of a uniform compensation system are administrative ease and horizontal equity. There are no calculations or subjective valuations and the system would treat every case identically. On the other hand, a uniform system is not vertically equitable because everyone would be paid the same amount regardless of her circumstances. Additionally, uniform compensation is unlikely to provide optimal incentives to all individuals.

The second approach would vest discretionary authority in the decision-maker to determine the appropriate amount of compensation. This approach would permit flexibility to consider individual circumstances. Finally, the third approach would confine the special master to determining damages from a damage table based on certain factors such as income and age. This would reduce the administrative burden of calculating damage awards while providing some consideration for differences between individuals.

In applying these principals there are three levels of compensation: medical expenses, pain and suffering, and economic damages. Clearly any compensation system should pay for unpaid medical expenses. All three historical approaches to compensation include medical expenses in the compensation determination. Certainly, a system for uniform payment would be extremely unfair because side effects greatly vary in severity. Alternatively, the program could completely indemnify the injured party or it could provide the average expense for the injuries. Both approaches would be administratively easy. Additionally, total reim-

bursement would reduce the possibility of an injured individual receiving substandard care. On the other hand, it provides an incentive for the injured party to overutilize care and for the provider to overprovide care. Alternative approaches would be prospective payment systems similar to Medicare reimbursement or a statutory mandate to only reimburse reasonable charges. Clearly a limitation for reasonable charges would be the simplest to implement.

The second decision is the valuation of non-economic damages. Both the NCVIA and the 9/11 VCF place a presumptive value on non-economic damages at \$250,000. For the 9/11 VCF, the special master created this presumption because he did not want to judge the individual circumstances of the deaths. Certainly, the estimation of pain and suffering damages is difficult because of its inherent subjectivity. Nevertheless, there will be a wide-range of side effects in the Vaccination Plan. It would be horizontally inequitable to give an individual suffering from eczema vaccinatum the same recovery as the estate of a person who died from post-vaccinial encephelopathy. A good compromise would be to provide uniform pain and suffering damages to each injury on the injury table. For example, all individuals suffering post vaccinial encephelopathy would receive an identical amount that would be more than the compensation received by individuals suffering from eczema vaccinatum. This approach would strike a balance between equity considerations and administrability.

A more contentious issue is the valuation of economic damages. The 9/11 VCF is a paradigmatic use of the human capital method for determining economic damages. The income cash flows are projected over a person's lifetime and discounted into present dollars. While it is a theoretically pure approach to compensation, the public is very uncomfortable with the 9/11 VCF's economic valuations of life. While juries routinely engage in such calculations, the compensation fund creates a comparative framework. A fifty year-old individual earning \$50,000 per year can look at a table and find that the government values his life by one quarter of a 35 year-old earning \$100,000. Additionally, a compensation system appears to be a voice of the

state whereas jury awards seem more removed.

From a theoretical perspective, the human capital approach to economic valuation is the most pure.³¹³ Additionally, the human capital approach more closely approximates the optimal incentive structure. The optimal compensation is the amount that would make the first responder indifferent between receiving the vaccine with compensation for any injuries and not receiving the vaccine.³¹⁴ For a person to be indifferent between these choices, a compensation system must fully cover their economic and non-economic expenses.³¹⁵ These values vary by individual. As a result, it is necessary to calculate individual losses.

For example, the second phase of the Vaccination Plan encourages the vaccination of some doctors, nurses, paramedics, and policemen. A uniform compensation regime would either under-incent or over-incent participation in the program. If compensation was set at the optimal level for policemen, then it would under-incent doctors. On the other hand, if the compensation was set at the level for doctors, then it would over-incent the other professionals. Clearly, the most efficient compensation scheme would not provide uniform recovery.

As demonstrated by the extent of criticism over the 9/11 VCF, it is not enough to adopt the human capital approach. Rather there are many other issues that must be addressed.³¹⁶

³¹³See W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act* 52 STAN. L. REV. 547, 562 (2000). For policy decisions, economists use the statistical value of life because the victim is unknown ex ante. For wrongful death, the identity of the victim is known so the human capital approach is appropriate. *Id.*

³¹⁴It is possible that the optimal compensation is below this amount

³¹⁵There might be a third component. The economic damages would cover any lost income. In theory, the non-economic damages should make the person indifferent about the pain and suffering. The third component is a risk premium to compensate for forcing a person to bear the risks of the potential injuries.

³¹⁶The litigation of the 9/11 VCF highlights some of these considerations. See discussion *supra* Part VI Section C. The first problem is establishing a base salary to project into the future. In the lawsuit against the 9/11 VCF special master, plaintiffs argued that it was incorrect to not include the salary information for 2001. While it is important to use current income information, it is not clear that incomes from 1998 through 2001 would accurately reflect future income streams. To the extent that there was an income bubble during this time period, then the compensation system would overcompensate those individuals. On the other hand, this may not be a problem for first responders because their income may not have been inflated during the late-90's like they were for employees on Wall Street.

Another issue is the determination of the number of years left in the labor market. Currently, men average a longer work-life expectancy than women. The 9/11 VCF only used the data for males. Another issue is the determination of the proper growth rate for salaries. The rate varies by geography and job classification. The 9/11 VCF uses the national salary growth rate to determine the future income stream.

In conclusion, determining the appropriate compensation scheme is important and controversial. The success of the compensation program to encourage vaccinations depends on the program providing the appropriate level of compensation. This Article recommends reimbursement for out-of-pocket medical expenses. Additionally, it recommends uniform awards for pain and suffering depending on the side effect. Finally, it recommends the human capital method for determining economic losses.

7. Federal Program

A program administered at the Federal level benefits from economies of scale. The number of adverse reactions to the smallpox vaccine will be relatively small. Spread over fifty states, this number becomes much smaller. It would be an administrative burden to have fifty programs to provide compensation to a small number of individuals in each state.

Additionally, uniformity is important to the success of the vaccination program. Starting with the premise that the country needs a compensation program to reduce the downside of vaccinations, it follows that there must be a threshold compensation arrangement that provides the appropriate incentives to first responders. Presumably, a federal system would be at or above such a threshold. If the design of the compensation program is left to the states then the concern is some states will adopt programs below the threshold arrangement. These suboptimal programs would not fully incent first responders to receive the vaccinations. Assuming that the vaccination program is the appropriate defensive mechanism, this undervaccination will create a chink in the defensive armor.

Additionally, states would not fully internalize the costs of their undervaccination. Clearly, a smallpox attack in one state could spread to many states. In crafting a compensation regime, each state would only include their costs in the calculation. If neighboring states provided adequate remedies then the problem would be

magnified. Setting substantive regulations at the optimum level would eliminate this problem. Nevertheless there is still the benefit of administrative efficiency if the program is consolidated at the federal level. As a result, any compensation program would be best administered at the federal level.

8. Office of Special Masters

Having established the need for a compensation system and discussing its substantive contours, it is important to determine who will administer the program. There are several options. It could be administered through the court system, through a special appointment, or through existing framework. While each approach has potential benefits, the purpose of the system is most easily effectuated by using the special masters in the Court of Federal Claims.

Though the system would substantively alter the current tort regime, one possibility would be to allow the claims to be brought in federal court. The Swine Flu Act adopted this approach. One advantage is that judges are well equipped to handle these types of claims. On the other hand, the substantive provisions of the proposed compensation system reduce the complexity of the claims. Additionally, it may be an unwise use of resources to add cases to the dockets of currently overburdened courts. One way to alleviate administrative stress would be to consolidate the claims in one district court. Additionally, it would eliminate duplicative procedures. This approach would essentially codify the Swine Flu approach of consolidating through the JPML.

Another approach would be to appoint an independent special master to handle the claims. The 9/11 VCF adopts this approach. Advantages of this approach are administrative ease and establishing an expert to handle the claims. However, criticisms of this approach include a lack of transparency, a lack of accountability, and unfair results. These are legitimate concerns but they may be a structural problem with the 9/11 VCF rather than an intrinsic problem of special masters. There are several solutions. Meticulous minutes could

be kept and the special masters decision could be reviewable. Similarly, the statute could vest less discretion in the special master.

Despite these possible reforms, it is more sensible to use a currently established system. The NCVIA created an office of special masters within the Court of Federal Claims. Presumably, these officials are experienced at handling such claims. Additionally, the Court of Federal Claims and the Federal Circuit have appellate jurisdiction over decisions of the special masters decisions. One drawback is the backlog of cases under the NCVIA. A major criticism of the process is that it has not eliminated the slowness or uncertainty of the outcomes. Again, the slow nature of compensation from VICP might be from the program rather than inherent. There is currently significant legislative interest in improving the administrative aspect of the NCVIA. Hopefully, the implementation of a smallpox vaccine compensation program would coincide with improvement in the administration of the VICP.

9. Conclusion

This Article recommends a limited smallpox vaccine compensation program for vaccine injuries. Because of its similarities, it could be enacted most easily by amending the NCVIA. It would make recovery available to first responders and secondarily-infected individuals. The NCVIA Vaccine Table would be amended to include the smallpox vaccine and the common injuries arising from the vaccine. Unlike the NCVIA, there would be no alternative causes of action available for dissatisfied claimants against manufacturers. Rather, only the U.S. government could seek a right of contribution against vaccine manufacturers. Other differences from the NCVIA include the use of damage tables for economic damages and for pain and suffering. Finally, special masters in the Court of Federal Claims would hear the claims. Certainly, Congress should address some of the current issues with the VICP including the adversarial nature of the DOJ. Nevertheless, the NCVIA offers the best source for quick recovery by injured vaccinees.

B.

A New Development: House Bill No. 865

On February 13, California Representative Henry Waxman introduced a bill (the Waxman Bill) in the House that attempted to address various perceived shortcomings of President Bush's Vaccination Plan.³¹⁷ In addressing these deficiencies, the Waxman Bill seeks to achieve several purposes. First, the bill attempts to ensure that first responders will be able to receive health care through several provisions.³¹⁸ Several provisions mandate substantive benefits that would prevent private insurers from not covering smallpox vaccine injuries and leaving first responders without access to care. The proposed statute also requires states to provide all medically necessary care to any first responder who has not received compensation under the compensation program.³¹⁹ Additionally, the bill would amend ERISA to require employee health plans to not alter the level of coverage for vaccine side effects.³²⁰ Second, the bill tries to address the potential problem of employers discriminating against employees based on vaccination status. The bill would forbid employers from discharging employees for declining to receive the smallpox vaccine.³²¹ Finally, and most importantly for this Article, the bill would establish a "Smallpox Program" to compensate for smallpox vaccine injuries. Mechanistically, the Waxman Bill would amend the NCVIA to include the smallpox vaccine and would enable the Secretary of HHS to promulgate regulations to include smallpox in the VICP.³²² Compensation would be available to any individual suffering side effects listed on the Vaccine

³¹⁷In a statement, Representative Waxman stated that "workers are understandably reluctant to accept a vaccine to protect the public while being forced to face the consequences of an adverse reaction alone." *Title Smallpox Vaccine Compensation and Safety Act of 2003*, 149 Cong. Rec. E. 268 (Feb. 13, 2003). He also dismissed the availability of workers' compensation as "not adequate." *Id.*

³¹⁸*Smallpox Vaccine Compensation and Safety Act of 2003*, H.R. 865, 108th Cong. (2003).

³¹⁹*Id.*

³²⁰*Id.*

³²¹*Id.*

³²²*Id.*

Table after receiving the smallpox vaccine. The bill would also allow secondarily-infected individuals to file a claim.³²³

Many of the substantive provisions of the Waxman Bill must be added. For example, it does not provide a list of covered side effects. Rather, the Waxman Bill only calls for an amendment to the Vaccine Table without listing the conditions that should be included on the table. It explicitly does not allow recovery for minor scarring or local reactions.

The Waxman Bill is different from the traditional NCVIA process in several ways. Like the NCVIA, the Smallpox Program would not be the exclusive remedy because the Waxman Bill would allow claimants to file negligence actions under HSA Section 304. However, this approach differs from the NCVIA because the U.S. would be the defendant and the plaintiff would have to prove negligence. Nevertheless, similar to the NCVIA, individuals choosing to bring a claim under HSA Section 304 would first have to file a petition for compensation. Finally, funding for the Smallpox Program would be identical to the funding of HSA Section 304 actions rather than from the Vaccine Trust Fund established by the NCVIA.

The Waxman Bill would enact many of this Article's recommendations. Most notably, it would use the NCVIA as a template for recovery including the use of table causation and special masters. Additionally, compensation would be available to both individuals receiving the smallpox vaccine and secondarily-infected individuals. Perhaps the largest divergence is the Waxman Bill still permits recovery under HSA Section 304. This provision would allow individuals to file negligence claims under the FTCA if they were dissatisfied with their results. Certainly, this provision is better than allowing individuals to file claims against the manufacturer as permitted by the NCVIA. Nevertheless, it is encouraging that the legislature has taken the

³²³ *Id.*

initial steps to respond to the compensation problem.

C. Another New Development: The HHS Proposal

In response to the increasing public demand for compensation and the introduction of the Waxman Bill in the House, the HHS unveiled a competing plan (the HHS Proposal) on March 6, 2003.³²⁴ Presenting a much different approach than the Waxman Bill, the HHS modeled the system after the Public Safety Officers Benefit (the PSOB) program—an obscure statute established in 1976 to compensate law enforcement officers and firefighters seriously injured or killed in the line of duty. Using this law as a template, the HHS Proposal would make compensation available for certain injuries and cap benefits at \$262,100.³²⁵ This section outlines the proposed program and compares it with the Article’s proposed program and the Waxman bill.

The origin of PSOB began in the early 1970’s as an effort to attract more people to law enforcement positions. From 1965 to 1974, the number of law enforcement officers killed in the line of duty in the United States rose from 53 to 132.³²⁶ This trend meant officers were facing greater risks for little compensation in return. As a House committee report stated:

The physical risks to public safety officers are great; the financial and fringe benefits are not usually generous; and the officers are generally young with growing families and heavy financial commitments. The economic and emotional burden placed on the survivors of a deceased public safety officer is often very heavy.³²⁷

The burden on survivors was also severe because it was difficult to obtain appropriate levels of life insurance.

³²⁴United States Department of Health and Human Services, Press Release: HHS Proposes Smallpox Vaccination Compensation Plan (available at <http://www.hhs.gov/news/press/20030305.html>) [hereinafter HHS Proposal]

³²⁵*Id.*

³²⁶H. Rpt. 94-1032 at 3.

While police officers' salaries were low, their insurance premiums were extremely high.³²⁸ The increasingly high risks and correspondingly low compensation discouraged individuals from becoming law enforcement officers. Responding to this problem, Senator McClellan of Arkansas introduced the Public Safety Officers' Benefits Act of 1976.

The PSOB provides compensation to public safety officers or their survivors for death or permanent and total disability. To receive death benefits, a public safety officer must have (1) died (2) as a direct and proximate result of,³²⁹ (3) a personal injury,³³⁰ (4) suffered in the line of duty.³³¹ To receive permanent and total disability payments, a public safety officer must (1) be permanently and totally disabled,³³² (2) as a direct result of,³³³ (3) a catastrophic injury³³⁴ (4) in the line of duty.³³⁵ Claimants qualifying for either death benefits or permanent and total disability benefits receive \$262,100.³³⁶ There is no collateral offset for additional life insurance coverage.³³⁷ Rather, the PSOB provides compensation beyond any benefits received from other sources. However, benefits are unavailable under certain circumstances including intentional misconduct, voluntary intoxication, and grossly negligent conduct.³³⁸

Though the PSOB is an obscure statutory provision, the HHS Proposal would extend the PSOB program to the Vaccination Plan's first responders.³³⁹ Presumably, the PSOB already covered some first responders. More specifically, those employed as police officer or fire fighter would already be eligible for PSOB compensation if the vaccination were considered in the line of duty. The HHS Proposal would just extend death

³²⁸See *Public Safety Officers' Benefit Act: Hearing Before the Subcommittee on Criminal Laws and Procedures of the Committee on the Judiciary* 94th Congress, 94-816 (statement of Senator Strom Thurmont) at 21.

³²⁹See 28 C.F.R. §32.2(d).

³³⁰See 28 C.F.R. §32.2(e).

³³¹42 U.S.C. §3796.

³³²See 28 C.F.R. §32.2(h).

³³³See 28 C.F.R. §32.2(d).

³³⁴See 28 C.F.R. §32.2(f).

³³⁵See 28 C.F.R. §32.2(c).

³³⁶42 U.S.C. §3796.

³³⁷28 C.F.R. §32.18.

³³⁸See 42 U.S.C. §3796a.

³³⁹HHS Proposal, *supra* note 324.

benefits and the permanent and total disability benefits to all first responders covered by the secretary's declaration.³⁴⁰

There are several provisions in the HHS Proposal beyond the PSOB system. First, the HHS Proposal would compensate individuals for two thirds of their lost wages.³⁴¹ This provision becomes effective after the fifth day of missed with recovery capped at \$50,000.³⁴² Further, it would operate secondary to any recovery through workers' compensation or any disability insurance. Second, the HHS would compensate individuals for all reasonable out-of-pocket medical expenses.³⁴³ Again, this provision would only be available where other health insurance coverage would be unavailable.³⁴⁴

The HHS Proposal is similar to the Waxman Bill in several ways. First, it provides for supplemental health care coverage. Both plans would reimburse individuals who had insufficient health care coverage. Second, the proposals provide a death benefit, though they are different. Whereas the Waxman Bill offers \$800,000 for a death, the HHS proposal only provides \$262,100. Finally, both plans cover secondarily-infected individuals. Many of the differences involve the level of compensation. Most importantly, the cap on lost wages would severely limit recovery under the HHS proposal. Whereas the Waxman Bill would offer complete compensation for lost wages, the HHS proposal would provide a cap at \$50,000. For a young doctor permanently disabled by the vaccine, this difference could equal several million dollars.

Certainly, the HHS constructed their proposal to create uniformity rather than vertical equity. These provisions create administrative ease and control costs. In fact, administration officials were eager to note that the HHS Proposal would only cost \$20 to \$30 million per year.³⁴⁵ As a theoretical matter, however, this proposal under-incentivizes first responders because it does not fully compensate their losses. This undercompensation

³⁴⁰See HHS Proposal, *supra* note 324.

³⁴¹*Id.*

³⁴²*Id.*

³⁴³*Id.*

³⁴⁴*Id.*

³⁴⁵Ceci Connolly, *White House Agrees to Benefits for Health Workers Sickened by Vaccine*, WASH. POST, March 6, 2003, at A1.

affects both physicians and public safety officials with the \$50,000 cap amounting to less than one year of wages for most physicians and many police officers.

Whether this theoretical problem translates to an actual problem depends on the response of first responders. If they receive the vaccination in response to the HHS Proposal then the theoretical problem of underincentification is academic. However, the initial response from several unions is tepid. A representative of the American Nurse's Association stated, [w]e appreciate they recognize it's a problem, but there's a long way to go from what we're looking for.³⁴⁶ Certainly, the response of the unions should concern administration officials because union leaders have been a driving force in the initial call for compensation. The success of any program will partially depend on the ability to persuade these individuals of the merits of the plan. Nevertheless it is still too early to know the fate of the HHS Proposal.

D. Conclusion

This Part discussed several proposals for smallpox vaccine compensation programs. Both the Article's recommendation and the recent Waxman Bill use the NCVIA as a template. The key difference between these proposals is the Waxman Bill would allow suits under HSA Section 304 against the United States. The HHS Proposal uses the obscure PSOB as a framework for compensation. While it would cover medical expenses, the HHS Proposal would offer very limited compensation for lost wages.

It seems clear that the administration wants to contain costs. However, this objective is in direct tension with the goal of complete participation in the Vaccination Plan. The Waxman Bill and this Article's proposal would most likely result in complete participation but would result in high costs. The HHS Proposal would be cost effective but may not encourage people to receive the vaccine. Presumably, there is an optimum level of compensation between these two positions that would encourage vaccinations while controlling costs.

³⁴⁶ *Id.*

Hopefully, dialogue between industry representatives and administration officials will result in developing this optimum approach.

Part VIII: Conclusion

After the events of September 11th and the anthrax attacks, it is clear that the United States must be proactive in providing homeland security. Currently, one of the most significant threats is the potential for a bioterrorist attack. Addressing this concern, the White House unveiled the Vaccination Plan to better protect our country in the event of a smallpox attack. Despite mechanisms for expedient implementation, the Vaccination Plan has failed to vaccinate most of the designated first responders.

The biggest reason for this failure is that the current patchwork regime does not provide complete compensation coverage. By the statutory action of HSA Section 304, only negligence claims can be brought against the United States. Additionally, the availability of workers' compensation is unclear in many states. Current opinion suggests that the Vaccination Plan will be an unmitigated failure without comprehensive compensation for vaccine injuries.

As outlined in this Article, there are historical precedents for no-fault compensation systems. Drawing from these examples, this Article recommended a federal compensation program largely based on the NCVIA. Recent legislation by Representative Waxman would provide many of the features mentioned in this Article. A competing proposal by the HHS would offer less compensation but would also be much cheaper.

Regardless of the substantive provisions, public dialogue is important because it is the best way to protect our homeland security. Certainly, recent developments show administration officials and industry representatives moving in the correct direction. Hopefully, discussions over the next weeks will result in a satisfactory and democratic solution that provides adequate protection to us all.